# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# **FORM 20-F**

0 REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended June 30, 2005

OR

• TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the transition period from to

OR

• SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report \_\_\_\_\_

**COMMISSION FILE NUMBER 000-51122** 

# pSivida Limited

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

Western Australia, Commonwealth of Australia (Jurisdiction of incorporation or organization)

> Level 12 BGC Centre 28 The Esplanade Perth WA 6000

Australia (Address of principal executive offices)

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

None

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

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

Ordinary Shares American Depositary Shares each representing 10 Ordinary Shares and evidenced by American Depositary Receipts

The number of outstanding shares of each of the issuers' classes of capital or common stock as of December 31, 2005 was: 387,009,956 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No 🗵

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes o No 🗵

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

Indicate by check mark which financial statement item the registrant has elected to follow. Item 17  $\Box$  Item 18  $\boxtimes$ 

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No 🗵

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#### INTRODUCTION

In this annual report, except where otherwise indicated, the "company," "pSivida," "we," "us" and "our" refer to pSivida Limited and its consolidated subsidiaries. References to the "ADSs" are to our American Depositary Shares, and references to "Ordinary Shares" and "ordinary shares" are to our ordinary shares. We also make reference to our subsidiaries as follows: references to "pSiMedica" refer to pSiMedica Limited; references to "pSiOncology" refer to pSiOncology Pte Limited; and references to "AION Diagnostics" refer to "AION Diagnostics Limited".

On December 30, 2005 we completed the acquisition of Control Delivery Systems, Inc., which was renamed pSivida Inc. We make reference to Control Delivery Systems as "CDS" or as "pSivida Inc." generally depending on whether such reference relates to that company before or after the acquisition.

We prepare consolidated financial statements in Australian dollars in accordance with accounting principles generally accepted in Australia, and they are sometimes referred to herein as the "financial statements." In this annual report, references to "A\$" are to Australian dollars and references to "US\$" and "US dollars" are to United States dollars, except for in the financial statements, where references to "\$\$" are to Australian dollars and references to "US\$" are to United States dollars. On June 30, 2004, the Federal Reserve Bank of New York Noon Buying Rate was US\$0.6952 = A\$1.00 and on June 30, 2005 such exchange rate was US\$0.7618 = A\$1.00.

Our fiscal year ends on June 30, and references in this annual report to any specific fiscal year are to the twelve month period ended June 30 of such year.

BioSilicon<sup>TM</sup>, BrachySil<sup>TM</sup> and SIMPL<sup>TM</sup> are our trademarks. Vitrasert<sup>®</sup> and Retisert<sup>TM</sup> are Bausch & Lomb Incorporated's trademarks. AEON<sup>TM</sup>, CODRUG<sup>TM</sup> and Medidur<sup>TM</sup> are trademarks of pSivida Inc., formerly CDS. This annual report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

# FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements that involve risks and uncertainties. We use words such as "anticipates," "believes," "plans," "expects," "future," "intends" and similar expressions to identify such forward-looking statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable at this time, we can give no assurance that such expectations will prove to be correct. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Our 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 annual report, including, without limitation, with the forward-looking statements included in this annual report and specifically under Item 3.D, *Risk Factors*.

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

#### PART I

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

# ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

# **ITEM 3. KEY INFORMATION**

### A. SELECTED CONSOLIDATED FINANCIAL DATA

The following table presents our selected historical consolidated financial data as of the dates and for each of the periods indicated. The information set forth below is not necessarily indicative of future results and should be read in conjunction with Item 5, "Operating and Financial Review and Prospects", as well as our audited consolidated financial statements and the notes thereto appearing elsewhere in this annual report.

The selected consolidated financial data as of June 30, 2005 and 2004 and for each of the three years in the period ended June 30, 2005 have been derived from our audited consolidated financial statements and the notes thereto included elsewhere in this annual report. The selected consolidated financial data as of June 30, 2003, 2002 and 2001, for the year ended June 30, 2002 and for the period from December 1, 2000 (inception date) to June 30, 2001 have been derived from our audited consolidated financial statements and notes thereto which are not included in this annual report.

We prepare our 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
		Years ended			(Dec 1, 2000) to
	2005	2004 (In Austral	2003 ian Dollars except numbe	$\frac{2002}{1}$	June 30, 2001 (1)
STATEMENT OF FINANCIAL PERFORMANCE		(			
DATA:					
A-GAAP					
Revenues from ordinary activities	828,976	381,679	110,675	916,600	113,145
Depreciation and amortization expense	(1,029,382)	(39,360)	(37,835)	(38,502)	(11,681)
Research and development expense	(8,287,930)	(7,011,666)	(4,586,182)	(3,186,863)	(226,132)
Interest expense	—	(5,635)	—		—
Employee benefits expense	(1,040,007)	(1,238,381)	(522,977)	(22,999)	(25,486)
Foreign currency (loss) / gain, net	(1,623,484)	1,461,368	(1,203)	(995)	
Corporate office expenses	(3,973,892)	(1,066,981)	(318,806)	(1,664,265)	(701,576)
Loss from ordinary activities before income tax	(15,125,719)	(7,518,976)	(5,356,328)	(3,997,024)	(851,730)
Income tax expense relating to ordinary activities				_	
Net loss before outside equity interest	(15,125,719)	(7,518,976)	(5,356,328)	(3,497,024)	(851,730)
	2	2			

					Period from Inception of Development Stage
	2005	Years ended J		2002	(Dec 1, 2000) to
	2005	2004 (In Australia	2003 n Dollars except number o	2002 (f shares)	June 30, 2001 (1)
Net loss attributable to outside equity interest	399,196	3,835,771	2,591,175	1,806,604	113,229
Net loss	(14,726,523)	(3,683,205)	(2,765,153)	(2,190,419)	(738,501)
Loss per share — basic and diluted	(0.07)	(0.03)	(0.03)	(0.02)	(0.01)
Weighted average number of ordinary shares outstanding					
— basic and diluted	207,802,540	126,990,066	101,281,292	89,834,844	69,053,359
US GAAP (as restated for the years ended June 30, 2004 and 2003 (2))					
Revenue from ordinary activities	161,666	56,200	—	N/A	N/A
Net loss	(16,561,512)	(5,019,974)	(2,268,603)	N/A	N/A
Loss per share — basic and diluted	(0.08)	(0.04)	(0.02)	N/A	N/A
Weighted average number of ordinary shares outstanding					
— basic and diluted	207,802,540	126,990,066	101,281,292	N/A	N/A
	2005	2004	As of June 30, 2003	2002	2001 (1)
STATEMENT OF FINANCIAL POSITION DATA:					
A-GAAP					
Cash assets	12,892,061	31,350,656	1,180,134	5,051,509	3,270,093
Working capital	11,876,713	29,791,981	433,609	4,643,187	3,107,966
Total assets	82,035,313	40,367,058	7,175,342	11,273,860	9,247,729
Contributed equity	107,883,835	49,957,982	15,602,184	14,649,616	12,107,849
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	(24,103,801)	(9,377,278)	(5,694,073)	(2,928,920)	(738,501)
Total parent entity interest in equity	79,987,614	36,845,743	6,095,165	7,939,515	7,585,467
Total outside equity interest	_	1,583,200	204,354	2,773,306	1,376,663
Total equity	79,987,614	38,428,943	6,299,519	10,712,821	8,962,180
U.S. GAAP (as restated for the years ended June 30,					
2004 and 2003 (2))					
Total assets	100,063,276	41,295,099	8,220,492	N/A	N/A
Total equity	87,650,337	37,794,706	7,140,316	N/A	N/A
Contributed equity	117,798,149	51,030,718	15,428,635	N/A	N/A

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

(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 our audited consolidated financial statements included 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 US dollars 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 we refer to as the noon buying rate.

Month	High	Low
December 2005	0.7567	0.7261
November 2005	0.7451	0.7267
October 2005	0.7644	0.7436
September 2005	0.7731	0.7537
August 2005	0.7739	0.7469
July 2005	0.7661	0.7403

# The noon buying rate on January 13, 2006 was US\$0.7535 = A\$1.00.

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

### **B. CAPITALIZATION AND INDEBTEDNESS**

Not applicable.

#### C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

#### **D. RISK FACTORS**

The following risk factors, in addition to the other information and financial data contained in this annual report, should be considered carefully in evaluating our company and its business.

#### Risks related to our company and our business

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

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

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

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

pSivida was formed in 2000. As primarily a research and development company, we have incurred operating losses in every year of existence. Under A-GAAP we have 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, we had an accumulated deficit under A-GAAP of A\$27.9 million. We have not achieved profitability and expect to continue to incur net losses through at least 2007, and we may incur losses beyond that time, particularly if we are not successful in having BrachySil approved and widely marketed by that time. Even if BrachySil is approved and is being marketed at some point in 2007 or beyond, we may not achieve sufficient sales of BrachySil or any other product to become profitable at that time or at any other time. The extent of future losses and whether or how long it may take for us to achieve profitability are uncertain.

We recently acquired CDS which has incurred net losses in each of its last five fiscal years. As a result of the acquisition, we expect to receive royalties from sales of Vitrasert, CDS' first commercial product. However, such sales have declined in each of the past four years, and we do not expect that they will comprise a significant portion of our future revenue. We also expect to earn royalties from future sales of Retisert, but we are unable to predict the amount of such future royalties. CDS earned royalties from Retisert sales by Bausch & Lomb in the six months ended December 31, 2005 in an amount expected to be less than \$750,000.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

pSivida Inc., formerly CDS, has exclusively licensed its technology with respect to Vitrasert, Retisert and certain other ophthalmic uses to Bausch & Lomb, and with respect to Medidur for diabetic macular edema or DME and certain other ophthalmic uses to Alimera Sciences. Bausch & Lomb is responsible for funding and managing the development and commercialization of all products under its agreement with pSivida Inc. and can terminate the agreement at any time upon 90 days' written notice. Alimera Sciences and pSivida Inc. are jointly funding the development of products licensed under that agreement, and Alimera Sciences may terminate its agreement with pSivida Inc. if pSivida Inc. fails to make a development payment or may terminate the agreement with respect to a particular product if pSivida Inc. notifies Alimera that it has abandoned the product or upon 30 days' notice following pSivida Inc.' 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 pSivida Inc. While Bausch & Lomb has significant experience in the ophthalmic field and substantial resources, there is no assurance as to whether and the extent to which that experience and those resources will be devoted to pSivida Inc.'s technologies. Alimera Sciences was only incorporated in June 2003 and has limited resources. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize these products and proposed products, decisions, actions, breach or termination of these agreements by Bausch & Lomb or Alimera Sciences could delay or stop the development or commercialization of Retisert, Medidur for DME or other of our products licensed to such entities.

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

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

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

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

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

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

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

competitors may also have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances and manufacturing and marketing such products or technologies.

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

Our competitive position is based upon our ability to:

- create and maintain scientifically-advanced technology and proprietary products and processes;
- attract and retain qualified personnel;
- develop safe and efficacious products, alone or in collaboration with others;
- obtain patent or other protection for our products and processes;
- obtain required government approvals on a timely basis;
- manufacture products on a cost-effective basis; and
- successfully market products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In both domestic and foreign markets, our ability to commercialize our products will depend, in part, upon the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products. If our products are not considered cost-effective, third-party payors may limit

reimbursement. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. If government and third-party payors do not provide adequate coverage and reimbursement levels for uses of our products, the market acceptance of our products would be limited.

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

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

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

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

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

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

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

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

If and when it is required, we will attempt to acquire additional funding through strategic collaborations, public or private equity financings, capital lease transactions or other financing sources that may be available. Additional financing may not be available on acceptable terms, or at all. Additional equity financings could result in significant dilution to stockholders. Further, in the event that additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, each of which could have a material adverse effect on our business. See "— Risks related to our recent acquisition of CDS and other recent transactions — If the price of our ADSs does nor rise above the conversion price by the time payment on the convertible note becomes due, we may have to repay all or part of the funds received in the convertible note financing."

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

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

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

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

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

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

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

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

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

federal or state securities laws of the U.S., especially in the case of enforcement of judgments of U.S. courts where the defendant has not been properly served in Australia.

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

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

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

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

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

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

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

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

The rights of holders of ADSs with respect to voting of ordinary shares and the right to receive certain distributions may be limited in certain respects by the deposit agreement entered into by us and Citibank, N.A. For example, although ADS holders are entitled under the deposit agreement, subject to any applicable provisions of Australian law and of our constitution, to instruct the depositary as to the exercise of the voting rights pertaining to

the ordinary shares represented by the American Depositary Shares, and the depositary has agreed that it will try, as far as practical, to vote the ordinary shares so represented in accordance with such instructions, ADS holders may not receive notices sent by depositary in time to ensure that the depositary will be able to vote the ordinary shares. This means that holders of ADSs may not be able to exercise their right to vote. In addition, under the deposit agreement, the depositary has the right to restrict distributions to holders of the ADSs in the event that it is unlawful or impractical to make such distributions. We have no obligation to take any action to permit distributions to holders of our American Depositary Receipts, or ADRs. As a result, holders of ADRs may not receive distributions made by us.

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

Since December 2000, the price of our ordinary shares has ranged from A\$0.09 to A\$1.44 per share, and since January 27, 2005, the price of our ADSs has ranged from US\$4.15 to US\$12.14. The price of our common shares and ADSs may be affected by developments directly affecting our business and by developments out of our control or unrelated to pSivida. The biotechnology sector in particular and the stock market generally are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volume of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated or that bear a disproportionate relationship to operating performance. Our share and ADS prices and their trading volume may fluctuate based a number of factors including, but not limited to:

- clinical trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our proposed products, and any denials and withdrawals of approvals;
- competitive factors including new product ideas and technologies, clinical trial results and approvals of competitive products in our markets;
- advancements with respect to treatment of the diseases targeted by our proposed products;
- developments relating to collaborative partners including execution and termination of agreements, achievement of milestones and receipt of payments;
- availability and cost of capital and our financial and operating results;
- changes in reimbursement policies or other practices related to our proposed products or the pharmaceutical industry generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us and the biotechnology industry.

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

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

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

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

As of December 31, 2005, we have outstanding options to purchase 31,169,162 of our ordinary shares, representing 8.1% of the total outstanding ordinary shares. In 2005, we raised capital through the issuance of 665,000 ADSs and warrants to acquire 133,000 ADSs and issued a convertible note currently convertible into 2,112,676 ADSs together with warrants to acquire an additional 633,803 ADSs. In addition, under certain circumstances, the convertible note will become convertible into a larger number of ADSs and the accrued interest on the principal amount of the note may be converted, in either case, potentially resulting in the issuance of a substantially larger number of ADSs. We issued a further 15,983,661 ADSs to common and preferred stockholders of Control Delivery Systems, Inc. in our acquisition of that company. Exercise and conversion of these options, warrants and convertible securities would dilute existing shareholders. Further, we intend to continue to finance our operations through the issuance of equity securities, if feasible.

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

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

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

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

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

The following risk factors relate to our December 30, 2005 acquisition of CDS, as well as two recently completed transactions: (1) our US\$4.3 million private placement structured as a private investment in public equity, referred to herein as the PIPE, and (2) our US\$15 million convertible note financing, referred to herein as the convertible note financing. For a description of the CDS acquisition, the PIPE and the convertible note financing, see Item 8B, "Significant Changes."

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

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

- coordinating research and development operations in a rapid and efficient manner;
- combining platform technologies of disparate sources;
- demonstrating to collaboration partners that the merger will not result in adverse changes in technology focus or development standards;
- retaining key alliances with collaboration partners;
- absorbing costs and delays in implementing overlapping systems and procedures, including financial accounting systems and accounting principles;

- persuading employees that our business culture and that of CDS are compatible, maintaining employee morale and retaining key employees; and
- overcoming potential distraction of management attention and resources from the business of the combined company.

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

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

Under Australian Equivalents to International Financial Reporting Standards, or A-IFRS (effective from July 1, 2005 — See Item 5A, "Recently Issued Accounting Pronouncements Applicable to pSivida"), we will account for the merger using the purchase method of accounting. Under purchase accounting, we will record the market value of our ADSs, cash, and other consideration issued in connection with the merger and the amount of direct transaction costs as the cost of acquiring the business of CDS. We will allocate that cost to the individual assets acquired and liabilities assumed, including identifiable intangible assets, based on their respective fair values. Intangible assets generally will be amortized over a 12 year period on a straight line basis. Based on our preliminary allocation of the purchase price, which is subject to change based on the actual outcome of an independent valuation, the amount allocated to goodwill is expected to be approximately A\$30.6 million, the amount allocated to identifiable intangible assets is expected to be approximately A\$120.0 million, giving rise to a gross deferred tax liability of approximately A\$48.0 million (approximately A\$29.1 million net of deferred tax assets), and approximately A\$2.7 million is expected to 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 of the cash-generating unit to which goodwill has been allocated exceeds its recoverable value. If identifiable intangible assets were amortized in equal quarterly amounts over a 12 year period following completion of the merger, the amortization attributable to these items would be approximately A\$2.5 million per quarter and A\$10.0 million per fiscal year. As a result, purchase accounting treatment of the merger could increase our net loss or decrease our net income in the foreseeable future, which could have a material and adverse effect on the future

#### pSivida has incurred significant costs in connection with the merger.

We estimate that we have incurred direct transaction costs of approximately US\$2.6 million (approximately A\$3.6 million) associated with the merger, which will be included as a part of the total purchase consideration for accounting purposes. In addition, prior to completing the merger, CDS incurred direct transaction costs for accounting, investment banking and legal services of approximately US\$2.4 million (approximately A\$3.3 million), which are to be expensed in the period in which they are incurred. We believe the combined entity may incur charges to operations, which currently are not reasonably estimable, in the quarter in which the merger was completed or the following quarters, to reflect costs associated with integrating the two companies and that such charges may be material.

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

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

In addition, the merger may be subject to the antitrust laws of Australia or other foreign jurisdictions. Anti-competitive mergers or acquisitions in Australia are regulated under sections 50 and 50A of the Commonwealth Trade Practices Act, or TPA, which generally prohibits any acquisition of shares or assets which is likely to have the



effect of substantially lessening competition in a market in Australia. The Australian antitrust regulator, the Australian Competition and Consumer Commission, or ACCC, may on its own initiative apply to an Australian Court under that law in order to block a merger, or to obtain orders for the divestiture of assets, or for other remedies. A private party may also apply to an Australian Court under that law for a more limited range of remedies.

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

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

The resale by former CDS stockholders of pSivida ADSs after the merger could cause the market price of our ADSs to decline. In connection with the merger, we have issued approximately 16,000,000 ADSs. While our ADSs will not initially be freely tradable, we have agreed to register their resale within six months (subject to certain extensions) for stockholders entering into the registration rights agreement. Therefore, approximately 16,000,000 pSivida ADSs issued in the merger are expected to become freely tradable under U.S. securities laws six months from the closing date of the merger, which was December 30, 2005. However, certain shareholders are subject to lock-ups for as long as 9 months after the closing date of the merger.

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

On November 16, 2005, we issued a subordinated convertible promissory note in the principal amount of US\$15 million (A\$19.7 million) to an institutional investor. The convertible note must be repaid in three payments of US\$5 million each which are due on or about November 16, 2006, May 16, 2007 and November 16, 2007 respectively, unless the convertible note is sooner converted into ADSs. The note is convertible into our ADSs at a conversion price of US\$7.10 per ADS, subject to adjustment based on certain events or circumstances, including the market price of ADSs for the ten trading days ending on May 5, 2006. The average trading price of our ADSs during the ten trading days ending on the day that is four trading days prior to the closing of the CDS acquisition was US\$5.087. If the price of our ADSs does not rise above the conversion price by the time any payment on the convertible note becomes due or if certain other requirements are not met, the right of pSivida to force conversion may not be exercisable and we may have to repay up to US\$5 million of principal, plus accrued interest at any one or all of these three dates. Given the cash needs of our business and the lack of current revenue, we cannot predict whether or not we will be able to meet this obligation if called upon to do so, or what impact this could have on our business and operations.

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

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

With respect to the PIPE, we are required to complete the registration no later than one hundred and eighty days from the date of the definitive agreements related to the PIPE, which places the deadline on or about February 23, 2006. If we fail to cause the registration statement registering the resale of ADSs to become effective beginning one month after this deadline, we may be subject to monthly cash penalties equal to one percent of the PIPE purchase price, or US\$43,225 (A\$59,200), until such registration statement becomes effective. With respect to the convertible note financing, we are required to complete the initial registration no later than one hundred and eighty days from the date of the applicable agreement, which places the deadline on or about May 16, 2006. Failure to comply with this deadline may result in pSivida having to pay monthly cash penalties equal to one and one-half percent of the convertible note purchase price, or US\$225,000 (A\$308,200), until the registration statement becomes effective. With respect to the acquisition of CDS, we are required to complete the registration no later than one hundred and eighty days from the closing of the merger, which would be on or about June 30, 2006. Failure to comply with this deadline may result in pSivida having to pay monthly cash penalties equal to one percent of the average closing price of the ADSs during the ten trading days ending on the day that is four trading days prior to the closing of the merger, multiplied by the number of outstanding unregistered ADSs, until the registration statement becomes effective. The average trading price of ADSs during the 10-day period just described was US\$5.087, which indicates that such penalties could amount to US\$813,089 (A\$1,113,700) per month. Each of these registration deadlines is subject to extensions in certain circumstances. Once the registrations are completed, we are obligated to keep them effective for specified periods, and failure to do so may subject us to additional penalties.

#### **ITEM 4. INFORMATION ON THE COMPANY**

### A. HISTORY AND DEVELOPMENT OF PSIVIDA

pSivida Limited is an Australian public company listed on the Australian Stock Exchange, the NASDAQ National Market, Frankfurt Stock Exchange and London's OFEX International Market Service and existing pursuant to the Australian Corporations Act 2001. Our corporate headquarters are located at Level 12 BGC Centre, 28 The Esplanade, Perth WA 6000, Australia and our phone number is (+61 8) 9226 5099. Our registered agent in the U.S. is the Corporation Service Company located at 1133 Avenue of the Americas, Suite 3100, New York, New York 10036. We also operate subsidiaries in the United Kingdom, Singapore, Australia and the United States.

The legal entity that became pSivida was incorporated as the Sumich Group Ltd in April 1987. The Sumich Group operated an agriculture business which was placed into administration or receivership on September 30, 1998. pSivida was subsequently formed on December 1, 2000 upon entering into a court-approved arrangement with Sumich Group's creditors which fully extinguished all prior liabilities as of that time. We then appointed new directors and officers and re-listed on the Australian Stock Exchange under our 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\$2,790,000.

Our principal capital expenditures (including acquisitions) in the past three years are described below. We have made no substantial divestitures in the past three years. Our acquisition of CDS is described under its own heading below.

- On October 13, 2003, we subscribed for additional convertible preference share capital in pSiMedica Ltd., increasing our direct ownership interest in pSiMedica by 3.4% to 46.25% with indirect effective control over 53.05%. The consideration paid by us in relation to this additional investment amounted to £2 million (approximately A\$4.84 million). This investment was required to fund continued research and development by pSiMedica.
- 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% of the issued share capital of pSiOncology.
- On August 4, 2004, we acquired the remaining shares in pSiMedica Ltd. that we did not already own. The consideration paid was A\$4,323,622 together with a total of 49,804,381 ordinary shares of pSivida issued at a value of A\$1.09. This amounted to total consideration equal to A\$58.6 million. In addition, 638,537 pSivida options with an estimated fair value of A\$292,828 were issued to employees of pSiMedica in exchange for their rights being waived in relation to options previously issued by pSiMedica. This amounted to total consideration equal to A\$59.2 million. As a result of this transaction QinetiQ Group plc, one of Europe's largest science and technology companies and the principal shareholder (besides pSivida) of pSiMedica, became our largest shareholder holding 17.5% of our issued capital at that time.



On August 24, 2004, we incorporated AION Diagnostics Limited in Australia to develop and commercialize diagnostic applications of BioSilicon. We intend to license diagnostic and sensor applications of the BioSilicon platform technology developed by AION Diagnostics. We capitalized AION Diagnostics with A\$1.2 million. In addition, zero exercise price options have been created over 20% of the issued capital to be awarded to directors, staff and consultants of AION Diagnostics, subject to the achievement of milestones.

#### Acquisition of CDS

On October 3, 2005, we entered into a merger agreement with CDS, a Boston-based company engaged in the design and development of drug delivery products. The merger agreement provided that a newly-formed subsidiary of pSivida would merge into CDS, with CDS surviving the merger as a wholly-owned subsidiary of pSivida with the name of pSivida Inc. After approval by the required majorities of both companies' shareholders and the fulfillment of other closing conditions, the merger was completed on December 30, 2005.

In exchange for their CDS shares, the former stockholders of CDS received 15,983,661 of our ADSs. Based on a price of A\$0.71 per share, the price prevailing upon the closing of the merger, the transaction represents a purchase price of approximately A\$118.8 million (US\$86.7 million). As at December 30, 2005, the ADSs received by the former CDS stockholders represented approximately 41.3% of the capital stock of the combined company. The former CDS stockholders will be subject to lock-up periods of no less than six months.

Certain former shareholders of CDS received cash rather than ADSs for their CDS shares. The total amount of such cash, which depended on the market value, on or about the date of the merger, of the ADSs that such shareholders would have received in the merger, was US\$83,116. This amount was paid out of our own funds, along with other costs of the acquisition. For a more detailed description of the acquisition and its effects, see Item 8B, "Significant Changes".

#### **B. BUSINESS OVERVIEW**

On December 30, 2005 we completed the acquisition of CDS, which was then renamed pSivida Inc. Due to the short amount of time since the completion of the acquisition, we have not yet integrated the business and operations of pSivida Inc. with the other business and operations of pSivida. Accordingly, information regarding the business of pSivida Inc. is provided separately from the information regarding the rest of pSivida's business. See "— Business of pSivida Inc." for information relating specifically to the business of pSivida Inc.

#### **Our Business**

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

#### **Our Commercialization Strategy**

Our 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 our internal product development is BioSilicon drug delivery, with an initial emphasis on brachytherapy products. Other potential BioSilicon drug delivery products are localized chemotherapy, slow release drugs and the delivery of generic drugs (commonly referred to as re-delivered generics). We have established detailed commercialization plans for BrachySil, our lead product, bearing in mind market sizes, benefits offered to patients and alternative competitive therapies. The first step in our 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 our 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. We also intend 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, we intend 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

We believe that the 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. We also intend to license diagnostic and sensor applications of the BioSilicon platform technology developed by our subsidiary, AION Diagnostics. In addition to licensing, we may also consider opportunities for collaborations.

On October 27, 2005 we signed a license with Beijing Med-Pharm Corporation for the clinical development, marketing and distribution of BrachySil in China. Under the terms of the license, we will manufacture BrachySil and Beijing Med-Pharm will be responsible for clinical development, securing regulatory approval, marketing and distribution in China. We will retain manufacturing rights for BrachySil under the license. It is a condition of the license that a manufacturing and supply agreement for us 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 (A\$2.7 million) and royalties ranging from 10% up to 30%, depending upon level of sales, payable to us by Beijing Med-Pharm.

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

We are 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. We believe that BioSilicon's features include:

- Biocompatibility BioSilicon is biocompatible, meaning that it is not injurious and does not cause immunological rejection within the body. We have 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 us 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 our clinical trials in Singapore.
  - To date, our human trials have produced no apparent product-related adverse events.
- Non-toxicity our studies have shown that BioSilicon degrades in the body into silicic acid, the non-toxic, dietary form of silicon which is found in beer, cereal grains and wine. We have undertaken both pre-clinical studies and clinical trials testing the toxicology of BioSilicon. our 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 We believe 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. We believe 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.
  - We have tested BioSilicon in a variety of buffered solutions (salty waters).

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

# Core Markets

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# 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. 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, we believe 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<sup>TM</sup>**

BrachySil, our lead product candidate, is a brachytherapy product that we believe 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. We have 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. We have tested BioSilicon in a variety of buffered solutions (salty waters).

We are developing products in this growing area through our 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 than that used in the earlier trials.

In addition, the Phase IIb trial will include a clinical evaluation of our proprietary SIMPL<sup>TM</sup> implantation system. SIMPL<sup>TM</sup> 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, we intend 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. We expect 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, we anticipate 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, we intend 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. we believe that such approvals may expand the market for brachytherapy.

During early 2006, we also intend 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. We are 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. We also intend to consult with government regulators in various other jurisdictions to promote this strategy.

#### Drug Delivery

We are also strongly focused on the application of BioSilicon technology to a controlled, slow release drug delivery product. We intend to achieve this through the development of our 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.

We also plan 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.

We have 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

In August of 2004 we incorporated AION Diagnostics in Australia to develop diagnostic applications for BioSilicon.

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.

We have assigned to AION Diagnostics a licensing agreement with Forschungszentrum Jülich for the use of our 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

We believe 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**

We believe 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. We are also examining the use of growth and disease inhibiting factors within the BioSilicon scaffold to assist with tissue regeneration. We are 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

In December 2005 we incorporated pSiNutria Limited in Australia to develop applications of our silicon technology in the food industry. pSivida Limited plans to license the use of BioSilicon<sup>™</sup> as an ingestible ingredient in food applications. pSiNutria is also developing patentable intellectual property using silicon in the food packaging area.

We have entered into an agreement with ITOCHU Corporation to explore the development and commercialization of new ingestible BioSilicon products in the 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. Our 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**

#### pSivida Inc.

On October 3, 2005, we entered into a merger agreement with CDS, a Boston-based company engaged in the design and development of drug delivery products. The merger agreement provided that a newly-formed subsidiary of pSivida would merge into CDS, with CDS surviving the merger as a wholly-owned subsidiary of pSivida with the name of pSivida Inc. After approval by the required majorities of both companies' shareholders and the fulfillment of other closing conditions, the merger was completed on December 30, 2005.

#### pSiMedica

In December 2000, we 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. We invested A\$1.0 million to acquire an 11.1% interest in pSiMedica. QinetiQ, which was formerly part of the Defence 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 Defence 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.

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

- In May 2001, we increased our 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 our 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, we 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 our holding an indirect 51.4% controlling interest in pSiMedica, and thereafter, we began to consolidate pSiMedica in our consolidated financial statements.
- On March 7, 2002, we subscribed for additional shares issued by pSiMedica. This had the effect of increasing our direct percentage ownership by 2.8% to 42.9% and indirect effective control to 50.8%. The consideration paid by us 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, we again subscribed for additional convertible preference share capital in pSiMedica, increasing our direct ownership by 3.4% to 46.3% with indirect effective control over 53.1%. The consideration paid by us 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, we acquired the remaining shares in pSiMedica that we 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 totaling \$321,342. As a result of this transaction QinetiQ became our largest shareholder, holding 17.5% of its issued capital at that time.

#### 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, we incorporated AION Diagnostics Limited in Australia to develop and commercialize diagnostic applications of BioSilicon. We have licensed diagnostic and sensor applications of the BioSilicon platform technology to AION Diagnostics. We 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 we and our 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 is seeking to develop products through strategic collaborations with universities, research institutions and industry partners and to obtain grant funding in Australia and the US.

#### pSiNutria Limited

On December 5, 2005, we incorporated pSiNutria Limited in Australia to develop applications of our silicon technology in the food industry. pSivida Limited capitalized pSiNutria with A\$1.5 million and will grant pSiNutria a royalty bearing exclusive license for the use of BioSilicon<sup>TM</sup> as an ingestible ingredient in food applications. pSiNutria is also developing patentable intellectual property using silicon in the food packaging area.

#### Collaborations

### QinetiQ

In connection with the organization of pSivida and pSiMedica, in December 2000, pSiMedica entered into a technology license agreement with the Defence 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 our making an additional investment in pSiMedica funded by our 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 retaining only the right to sublicense the intellectual property to DERA for noncommercial, defenserelated 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.

#### 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 whollyowned 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 we 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 32P-BioSilicon nano-structured micro particles to meet pSiMedica's commercial supply requirements. This facility was completed in September 2005.



# License Agreement with Beijing Med-Pharm

On October 27, 2005 we signed a license with Beijing Med-Pharm Corporation for the clinical development, marketing and distribution of BrachySil in China. Under the terms of the license, we will manufacture BrachySil and Beijing Med-Pharm will be responsible for clinical development, securing regulatory approval, marketing and distribution in China. We will retain manufacturing rights for BrachySil under the license. It is a condition of the license that a manufacturing and supply agreement for us to supply BrachySil to Beijing Med-Pharm is concluded within 90 days of October 27, 2005. The license includes upfront payments to pSivida of US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the manufacturing and supply agreement, and additional payments of up to US\$1,750,000 (approximately A\$2,400,000) if certain milestones are achieved. In addition, we will receive royalties ranging from 10% up to 30%, depending upon level of sales.

#### Top Five Global Pharma

On October 22, 2004, we entered into an agreement with an undisclosed top five global pharmaceutical company for the staged evaluation of BioSilicon as a delivery vehicle for selected compounds. The initial stage of the planned 12 month program has concluded, meeting the agreed technical success criteria, and triggering a payment to us 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.

#### **Cirrus Pharmaceuticals**

We recently entered into a contract with U.S.-based Cirrus Pharmaceuticals, Inc., an independent research and development 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 we 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 us.

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

We have 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 our porous BioSilicon technology successfully released MELANOTAN<sup>TM</sup> over a sustained period. The outcome of this collaboration may lead to a second-generation liquid-based injectable MELANOTAN<sup>TM</sup> product.

#### Forschungszentrum — Porous Silicon Mirror Technology

Our subsidiary, AION Diagnostics, is a party to 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

Together with the Flinders University of South Australia, we were 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

We 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

Our 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.

# 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

We currently produce BioSilicon<sup>™</sup> at our facilities at Malvern in the UK, and also have an option to acquire additional BioSilicon from QinetiQ in the UK for use in internal and collaborative research. Our 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. We require 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 ours, and the U.S. is the largest market into which we hope to be able to market BrachySil in the future. We intend to apply to the FDA to market BrachySil in the U.S., which will require FDA certification of our compliance with its regulations. We believe that our experience in manufacturing in compliance with FDA guidelines should facilitate the application process. To date, we have not sought nor have we 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, we have 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 32P.

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

We have developed BioSilicon production capability at our 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 32P-BioSilicon nano-structured microparticles to meet pSiMedica's commercial supply requirements. This facility was completed in September 2005.

#### **Intellectual Property**

We believe that we enjoy a strong intellectual property position, with core biomaterial patents granted in the valuable United States and European markets. We own all intellectual property rights in relation to BioSilicon for which there are as at December 31, 2005, 36 granted patents, 31 patent families and over 90 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 we 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 we 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 issued at a value of A\$1.09 per share.

Our patent portfolio comprises patents and 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 our core focus of specialized drug delivery, targeted internal cancer therapy, diagnostics and the use of silicon in food and pharmaceuticals.

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.

The following table provides general details relating to our patents and patent applications; it is based on information available on December 31, 2005. The table does not include patents and patent applications held by CDS (now pSivida Inc.) and acquired by us in the acquisition of CDS on December 30, 2005.

# Table of Contents

Priority Number	Status	Subject Matter	
9515956.2	National applications (EP, JP, CA) <b>Granted (GB1, GB2, US1, US2, KR1, 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.	
9909996.2	National applications (CA, CN, JP, KR, US) Granted (AU, EP, NZ)	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) Granted (SG, AU, EP)	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) Granted (EP, NZ, AU, SG)	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) Granted (NZ, AU, US1, SG) Accepted (US2)	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	National applications (EU, JP) Granted (US)	The claims relate to substantially monodispersed (having the same size or shape) porous silicon particles.	
0014079.8	National applications (US, JP, SG) <b>Granted (AU1, EP1)</b> Divisional (AU2, EP2)	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) Granted (EP, NZ, AU)	The claims relate to dermatological compositions comprising porous and/or polycrystalline silicon.	
0104383.5	National applications (US, AU, CA, JP, EP) Granted (NZ, SG)	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 (JP, EP, SG) Accepted (AU, US1) Divisional (US2)	The claims relate to sweat patches, including patches comprising electronic circuitry, for the collection and detection of sweat components.	
0130608.3	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.	

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Priority Number	Status	Subject Matter
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.
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	International application (all PCT states)	The claims relate to a chronotherapeutic device.
0423383.9	International application (all PCT states) + Taiwanese 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.
0519066.5	Priority Application	The claims relate to an analytical device for testing body fluids.
0519391.7	Priority Application	The claims relate to tissue markers and contrast agents comprising porous silicon
0526332.2	Priority Application	The claims relate to a pharmaceutical product comprising an excipient that melts at 37C.
Not yet known	Priority Application	The claims relate to a composition comprising porous silicon having one or more beneficial organic substances covalently linked to the silicon surface.

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.

We have strengthened our intellectual property portfolio with the granting of an additional 10 patents during the past year. In August 2005, we were granted our 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.

We were also granted our first patents in China and Korea. We believe 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.

The two Korean patents provide protection for bioactive and resorbable silicon together with the electronic-based properties of BioSilicon in the stimulation of orthopedic tissue repair and re-engineering. The technology also has application for treatment of fractures that do not heal, such as "bone non-union". We believe 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. We hope to capitalize on Korea's technology strengths as well as the higher margins associated with healthcare products.

We believe that pSivida enjoys a strong intellectual property position, with core biomaterial patents granted in the valuable United States and European markets. Granted patents are held for each of our first three inventions that cover the broad use of BioSilicon in healthcare applications, we own all intellectual property rights in relation to BioSilicon for which there are as at December 31, 2005, 36 granted patents, 31 patent families and over 90 patent applications. QinetiQ, as a former agency of the United Kingdom government, under the terms of the initial Intellectual Property assignment, is required to assist in the defense of any challenge to the initial core patents.

#### Sales and Marketing

We have no experience in the sales, marketing and distribution of healthcare products. If in the future we fail to reach or elect not to enter into an arrangement with a collaborative partner with respect to the sales and marketing of any of our future products, we 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 us to develop such a sales and marketing organization.

#### Competition

We are 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 ours are marketing or may develop products that directly compete with any products we may develop. These entities may succeed in developing products that are safer, more effective or less costly than products we may develop. Even if we can develop products which should prove to be more effective than those developed by other companies, other companies may be more successful than us 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 we commence significant commercial sales of any products, we or our collaborators will compete in areas in which we have no experience, such as marketing. There can be no assurance that our products, if commercialized, will be accepted and prescribed by healthcare professionals.

Our 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. We do not know of any other company that is developing a non-polymer — i.e., pure element — drug delivery system.

### Revenue

The following table details the revenue recognized by the company by type and by geographical location for the years ended June 30, 2005, 2004 and 2003.

		Years Ended June 30		
	2005	2004 (In Australian Dollars)	2003	
Interest income on bank deposits				
Australia	636,035	250,427	25,065	
United Kingdom	28,276	64,130	72,729	
Singapore	2,999	10,922	12,881	
Total interest income on bank deposits	667,310	325,479	110,675	
Other revenue				
Australia	—	888	_	
United Kingdom	161,666	55,312	—	
Singapore		—		
Total other revenue	161,666	56,200		
Total Revenue	828,976	381,679	110,675	

## Business of pSivida Inc.

On December 30, 2005 we completed the acquisition of a 100% interest in Control Delivery Systems, Inc., which was then renamed pSivida Inc. Because of the short amount of time since the completion of the acquisition, we have not yet integrated the business and operations of pSivida Inc. with the other business and operations of pSivida. The following information relates only to the business of pSivida Inc.

#### Overview

pSivida Inc. designs and develops innovative sustained-release drug delivery products. Our two proprietary drug delivery systems, AEON and CODRUG, deliver specific quantities of drugs directly to a target site in the body at controlled rates for predetermined periods of time ranging from days to years. These systems are designed to address drawbacks of systemic drug delivery for our target diseases: adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site.

pSivida Inc. has two commercial products utilizing the AEON system approved by the 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 DME, another leading cause of vision loss. Medidur, an injectable AEON product, is also designed to treat DME and is currently in fast-track Phase III clinical trials conducted by Alimera Sciences Inc. pSivida Inc. also has two AEON product candidates in pre-clinical studies for other back of the eye diseases.

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



pSivida Inc.'s products and product candidates are currently at the following stages of development for the listed diseases:

Disease	Stage of Development
AEON System	
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
CODRUG System	
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 systematically 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 MacugenÔ (pegaptanib sodium) and LucentisÔ (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 pSivida Inc. Technology Systems

pSivida Inc.'s 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. The delivery systems
  of pSivida Inc. 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. We believe that this allows the products and product candidates of pSivida Inc. to maintain the optimal drug concentration at a target site and eliminate variability in dosing over time.
- Extended Delivery. The AEON and CODRUG systems deliver drugs for predetermined periods of time ranging from days to years. We believe 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, pSivida Inc. can control both the rate and duration of release to meet different therapeutic needs. We believe that the AEON system might be used to deliver a wide variety of different drugs. pSivida Inc. is currently using AEON technology for all of its ophthalmic products and product candidates. As of the date of this annual report, pSivida Inc. either has, or has exclusive licenses to, 34 issued patents and 133 patent applications covering different aspects of its AEON technology.

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. pSivida Inc. is working to develop a bioerodible Medidur system.

## CODRUG Technology

pSivida Inc.'s 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, pSivida Inc. 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. We believe that many drugs can be chemically linked with our CODRUG technology and has synthesized a library of approximately 298 CODRUG compounds. pSivida Inc. 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 annual report, pSivida Inc. either has, or has exclusive licenses to, three issued patents and 69 patent applications covering its CODRUG technology.

### Products and Product Candidates of pSivida Inc.

pSivida Inc.'s 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 sight-threatening diseases. pSivida Inc. also has AEON product candidates for DME, dry age-related macular degeneration, or AMD, and retinitis pigmentosa, or RP, three other sight-threatening diseases.

pSivida Inc. 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*. Our 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. pSivida Inc.'s 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. Our 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 seven-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.

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 preimplantation 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. pSivida Inc.'s 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 and a leading cause of vision loss for Americans under 65. We are 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, pSivida Inc. 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. 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 two years, and fewer patients 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. We are unable to predict the outcome of these trials at three years. pSivida Inc. has licensed the rights with respect to Retisert for DME to Bausch & Lomb.

Dry Age-Related Macular Degeneration. pSivida Inc. 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.* pSivida Inc. 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. pSivida Inc. 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.* pSivida Inc. 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 oneinch 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.

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

pSivida Inc. 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, pSivida Inc. retains its rights to the underlying technologies.

### Chiron Vision Corporation

pSivida Inc.'s 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 pSivida Inc. 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 pSivida Inc. royalties on net sales of Vitrasert under its current agreement, described further below.

#### Bausch & Lomb Incorporated

In 1999, pSivida Inc. entered into a licensing and development agreement with Bausch & Lomb for additional products for the treatment of eye diseases. pSivida Inc. 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, pSivida Inc. granted Bausch & Lomb a worldwide, exclusive license to certain of pSivida Inc. technologies to make and sell Vitrasert and pSivida Inc.'s 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 pSivida Inc. royalties based on net sales for any products that meet the definition of first generation products.

pSivida Inc. 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 did 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, pSivida Inc. may terminate the non-exclusive license for such product (unless this breach is cured within 90 days of receipt of notice). We are not aware as to whether Bausch & Lomb has commenced an IND for any such product. If Bausch & Lomb does market such products, it will pay pSivida Inc. 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 pSivida Inc. specified amounts if it achieved certain milestones related to certain licensed products.



pSivida Inc. 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 pSivida Inc. 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 pSivida Inc. a specified level of royalty. pSivida Inc. 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 pSivida Inc. technologies.

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 pSivida Inc. 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 pSivida Inc.'s intellectual property to make and sell the relevant product.

## Alimera Sciences Inc.

In February 2005, pSivida Inc. granted Alimera Sciences a world-wide exclusive right to use certain pSivida Inc. 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, pSivida Inc. granted to Alimera Sciences a world-wide exclusive right to use certain pSivida Inc. 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. pSivida Inc. 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 pSivida Inc. 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 pSivida Inc. 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 pSivida Inc., 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 pSivida Inc. technologies are jointly owned by Alimera Sciences and pSivida Inc., 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 pSivida Inc. In the future, pSivida Inc. may independently commercialize and sell some of its other products. In appropriate cases, pSivida Inc. may also enter into joint marketing or license arrangements for other products.

#### Reimbursement

The successful commercialization of pSivida Inc.'s 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 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

pSivida Inc.'s 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. pSivida Inc. therefore seeks, whenever possible, to obtain protection for these products and processes. pSivida Inc. also seeks to expand our product and process portfolio through collaborations, funded research and licensing technology from others.

#### Patents and Patent Applications

pSivida Inc. 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 annual report pSivida Inc. has, or has exclusive rights to, 12 United States patents and 26 foreign patents. In addition, as of the date of this annual report, pSivida Inc. has, or has exclusive rights to, 42 patent applications pending in the United States and 167 patent applications pending in foreign countries. pSivida Inc.'s 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 pSivida Inc.'s technologies. pSivida Inc. 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 pSivida Inc.'s 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, pSivida Inc. has chosen or may chose 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, pSivida Inc. 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 pSivida Inc. to protect its proprietary information by controlling the disclosure and use of technology to which pSivida Inc. has rights, and to provide for its ownership of proprietary technology that pSivida Inc. 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, pSivida Inc. expects that its proposed products, if approved, will compete with existing therapies for pSivida Inc.'s 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.



We expect that pSivida Inc.'s 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. We believe that pharmaceutical, drug delivery, and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations, and individual scientists are seeking to develop therapies for pSivida Inc.'s 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 pSivida Inc. will or may compete are much larger, have much greater financial resources and have much more experience in drug development and sale than pSivida Inc.

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<sup>®</sup> 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 pSivida Inc. 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 pSivida Inc. 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 TazoracÒ cream and gel and Bristol-Myers Squibb Co.'s DovonexÒ 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 SoriataneÒ 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 EnbrelÒ (Amgen, Inc.) and RaptivaÔ (Genentech, Inc. and Xoma, Inc.) injectable products. If pSivida Inc. 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 cautery, cryosurgery and chemical peels.

## Legal Proceedings

A potential lender to pSivida Inc. has claimed a break-up fee as a result of the royalty advance agreement between pSivida Inc. and Bausch & Lomb. An investment banker has claimed an advisory fee in connection with that agreement as well as the acquisition of pSivida Inc. by pSivida. We intend 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 pSivida Inc.'s 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 pSivida Inc. 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 pSivida Inc. 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.
- 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. pSivida Inc. cannot be certain that it will successfully complete Phase I, Phase II or Phase III testing of pSivida Inc.'s product candidates within any specific time period, if at all. Furthermore, pSivida Inc., 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. 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.

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 pSivida Inc.'s 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.

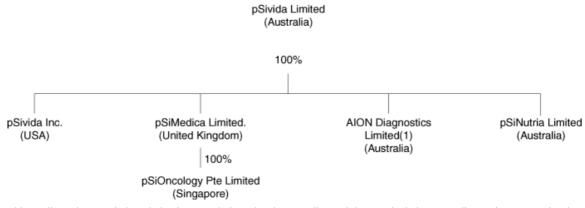
Any products pSivida Inc. manufactures or distributes under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required 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 pSivida Inc. and its third-party manufacturers.

pSivida Inc. 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. pSivida Inc. may incur significant costs to comply with such laws and regulations now or in the future. In addition, pSivida Inc. cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

pSivida Inc. also is subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products which pSivida Inc. 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 pSivida Inc. 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.

# C. ORGANIZATIONAL STRUCTURE

As at December 31, 2005, pSivida had the organizational structure diagrammed below.



(1) The 100% ownership applies only to capital stock that is currently issued and outstanding and does not include outstanding options to acquire shares of AION Diagnostics currently held by directors and employees of AION Diagnostics, of which options over 7.9% of capital, calculated on a fully diluted basis, have vested.

### D. PROPERTY, PLANT AND EQUIPMENT

We own computer equipment, office furniture and lab equipment, the majority of which are used in our Malvern laboratory facilities. We lease approximately 223 square meters of laboratory space and 449 square meters of office space in Malvern, United Kingdom, approximately 305 square meters of office space in Perth, Western Australia and approximately 366 square meters of laboratory space, 147 square meters of cleanroom space and 733 square meters of office space in Boston, Massachusetts.

Our manufacturing partner QSA, has completed the construction and validation of a state-of-the-art cleanroom facility, dedicated to the supply of our lead cancer therapy BrachySil, at QSA's Auriga Medical<sup>TM</sup> 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.

# ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis in conjunction with Item 3A, Selected Consolidated Financial Data, and the audited consolidated financial statements and other financial information appearing elsewhere in this annual report. In addition to historical information, the following discussion and other parts of this annual report contain forward-looking statements that reflect our plans, estimates, intentions, expectations and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. See the Risk Factors section of Item 3 and the warnings associated with the other forward-looking statements in this annual report for a discussion of some, but not all factors, that could cause or contribute to such differences.

### A. OPERATING RESULTS

# Overview

We are a development stage enterprise at an early stage in the development of BioSilicon and other technologies. We currently have two products approved for sale and being sold, Vitrasert for CMV retinitis and Retisert for posterior uveitis. We have incurred net losses since inception and expect to incur substantial and increasing losses for the next few years as we expand our research and development activities and move our other product candidates into later stages of development. All of our BioSilicon product so f development and we face the risks of failure inherent in developing drugs based on new technologies. The process of carrying out the development of our BioSilicon 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, we have funded our operations primarily through private placements of equity securities, the exercise of options and share purchase plans.

Our revenues are generated in both Australian dollars and Pounds Sterling, and a majority of our expenses are incurred in either Australian dollars, Pounds Sterling or U.S. dollars.

The following information is presented on an A-GAAP basis, unless otherwise noted.

#### **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.

	2005	2004	2003
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.

# 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, our 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 our 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 our NASDAQ listing in January 2005 and the associated increase in US regulation and 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, we recognized A\$161,666 as other income in the 2005 period, compared with A\$56,200 of other income in the 2004 period, in connection with the research being undertaken by EpiTan and pSivida's top 5 global pharmaceutical company collaboration partner.

# **Depreciation and Amortization Expense**

Depreciation and amortization expense (excluding depreciation of plant and equipment used in research and development activities) increased to A\$1.0 million 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 2,515.3%. 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 us because our intangible assets have not led to a product at a commercial production stage of development. We recognized

goodwill amortization expense of \$973,923 for the year as a result of the acquisition of the remaining outside equity interest in pSiMedica Limited in August 2004, 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 or 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 our 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.

### **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.

### Foreign Currency

An unrealized foreign exchange loss of A\$1.6 million was recognized during the year ended June 30, 2005 compared to an unrealized foreign exchange gain of A\$1.5 million during the year ended June 30, 2004. This was primarily 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 us other than in Australian dollars.

### **Corporate Office Expenses**

Corporate office expenses increased to A\$3.9 million for the year ended June 30, 2005 from A\$1.1 million for the year ended June 30, 2004, an increase of A\$2.9, or 272.4%. This increase is primarily due to our 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, our 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, we recognized A\$56,200 as other income in the 2004 period (up from zero in the 2003 period) in connection with research being undertaken by EpiTan.

# 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 us because our 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 our expenditure on the completion of pre-clinical trials of BrachySil and human clinical trials of BrachySil which commenced during 2004 in Singapore.

### **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 we required as a result of increased levels of research and development activity and additional finance and administration resource requirements.

#### Foreign Currency

An unrealized foreign exchange gain of A\$1.5 million was recognized during the year ended June 30, 2004 compared to an unrealized foreign exchange loss of A\$1,203 during the year ended June 30, 2003. This was primarily due to favorable 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 us other than in Australian dollars.

#### **Corporate Office Expenses**

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 our further development during the year.

#### Inflation and Seasonality

Our management believes inflation has not had a material impact on our operations or financial condition and that our operations are not currently subject to seasonal influences.

## **Foreign Currency**

Based on Pounds Sterling and U.S. dollar account balances at June 30, 2005, the following table shows the sensitivity of our 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.

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

We do not utilize financial derivatives instruments or other financial instruments subject to market risk.

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# Quantitative and Qualitative Disclosures About Market Risk

We have exposure to changes in foreign currency exchange rates and interest rates. We do not utilize derivative financial instruments or other financial instruments subject to market risk.

# **Government Regulation**

There are no regulatory or fiscal policies under the governments of either Australia or the United Kingdom which would adversely affect our operations

# **Conditions in Australia**

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

# 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

We will be required to prepare financial statements that comply with Australian Equivalents to International Financial Reporting Standards, or AIFRS, for annual reporting periods beginning on or after January 1, 2005. Accordingly, our first half-year report prepared under AIFRS, as adopted by the Australian Accounting Standards Board will be for the half-year reporting period ended December 31, 2005, and our 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", or AASB 132 and AASB 139: "Financial Instruments: Recognition and Measurement", or 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 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 June 30, 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 July 1, 2004).

In 2004, we 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, our transition date to AIFRS. This will form the basis of accounting for AIFRS in the future and is required when we prepare our first fully AIFRS-compliant financial report for the year ending 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 effective 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 effective 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 AASB 3: "Business Combinations", or AASB 3, 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", or AASB 2, 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", or AASB 1. 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, 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 June 30, 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 July 1, 2004.

#### (ii) Share-based payments

Under AASB 2, 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 yet to determine whether 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. July 1, 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 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", or AASB 136, 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 our review process we are 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 we 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", or AASB 127 requires minority interests to be classified as equity. Consequently our acquisition of additional ownership interests in pSiMedica Limited 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: "Accounting for Stock Issued to Employees", or APB 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, we 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 our 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", or SFAS 153, which amends APB Opinion No. 29: "Accounting for Nonmonetary

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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 our financial position or results of operations.

In May 2005, the FASB issued SFAS No. 154: "Accounting Changes and Error Corrections," or SFAS 154, which replaces APB Opinion No. 20: "Accounting Changes" and SFAS No. 3: "Reporting Accounting Changes in Interim Financial Statements". The standard is 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 our financial position or results of operations.

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

We prepare our 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 our net loss and total equity in accordance with A-GAAP and U.S. GAAP as of the dates and for the periods indicated:

	Years ended June 30,	
2005	2004	2003
(14,726,523)	(3,683,205)	(2,765,153)
	( )   )   ) /	
(16,561,512)	(5,019,974)	(2,268,603)
	As at June 30,	
2005	2004	2003
79,987,614	38,428,943	6,299,519
87,650,337	37,794,705	7,140,316
	(14,726,523) (16,561,512) 2005 79,987,614	$\begin{array}{c cccc} \hline & & & & & & & & & & \\ \hline & & & & & & &$

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 for the years ended June 30, 2005, 2004 and 2003 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 our June 30, 2004 consolidated financial statements, we 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. We have subsequently concluded that, although under tax law we 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 we 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 establishing a valuation allowance, we 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 described above, we have reevaluated the recoverability of the deferred income tax assets, taking into consideration the reversal of taxable temporary differences under the 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 assets for U.S. GAAP purposes.

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

#### **Critical Accounting Policies**

We prepare our audited consolidated financial statements in accordance with A-GAAP. As such, we are required to make certain estimates, judgments, and assumptions that management believe 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 believe are the most critical to aid in fully understanding and evaluating our 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 us 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 Defence 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.

We 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 us 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 us 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, we 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 we completed the acquisition of the pSiMedica shares that we did not already hold such that we now hold 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, 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, pSiMedica has been granted significant patents and it was thought appropriate that this position be reviewed. Based on management's assessment at the date of acquisition, the total amount of the incremental increase in the value of intangible assets of A\$25 million should be attributed to the patents granted since October 2003. Consequently, based on management's assessment we recognize 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 our 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 us 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 our 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 and patents.

Our 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 commercial production of products calculated on a straight-line basis over the remaining balance of the estimated useful life. We review 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 our 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 our future financial performance in which the deferred tax asset is recognized. On this basis we have not achieved profitability and expect to continue to incur net losses through to 2007. As we do not expect BrachySil to be widely marketed before then, no tax asset has been recognized.

## **B. 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. We have financed our operations primarily through private placements of equity securities, the exercise of options and share purchase plans. With the exception of a convertible note entered into by us on November 16, 2005 we have utilized no borrowings since December 1, 2000 and we do not anticipate utilizing any borrowings in the near future. We have no off-balance sheet financing and we expect that our current cash levels will be sufficient to support current levels of research and development until the second quarter of calendar year 2007.

However, we may increase our level of research and development activity which will directly increase our need for cash reserves as research and development is our most significant cost driver. We have reported negative cash



flows from operations and we expect this to continue at least until the end of 2006, as we are in the development stage and have not yet commercialized most of our products, including BrachySil.

On April 20, 2004, we 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, we 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 we raised US\$4.3 million (A\$5.7 million) before costs via the private placement of 665,000 ADRs to predominantly U.S. investors at US\$6.50 (A\$8.61) each, pursuant to a PIPE.

On November 16, 2005 we 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 "Business Overview" for a detailed description of our 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 we 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 we incurred \$27,422 in issue costs in relation to the acquisition of the remaining outside equity interest in pSiMedica in August 2004.

- Cash flows from financing activities during the year ended June 30, 2004 reflected the following:
- On August 4, 2003, we issued 3,891,572 ordinary shares at A\$0.24 per share, raising A\$932,298 net of issue costs. On October 6, 2003, we 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, we 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, we 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, we 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 us 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, we 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.

On September 12, 2002, we 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 us 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 us on this facility.

From commencing business as a development stage enterprise to June 30, 2005, our capital expenditures have totaled A\$4.8 million consisting of computer equipment and laboratory equipment that is being used in connection with our 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. We do not have significant capital spending requirements, but expect to continue to engage in capital spending consistent with anticipated growth in operations and personnel. Capital expenditure has been funded largely through the private placement of ordinary share capital.

We believe that our existing cash and cash equivalents will be sufficient to support our current operating plan until the second quarter of calendar year 2007. However, we have based this expectation on assumptions that may prove to be incorrect. Our future funding requirements will depend upon many factors, including, but not limited to:

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

# C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES, ETC.

Our primary activity is the development of products based on nano-structured BioSilicon. Our research and development expenses were A\$8.3 million, A\$7.0 million and A\$4.6 million during the years ended June 30, 2005, 2004 and 2003 respectively. These research and development expenses consist primarily of compensation and related costs for research and development personnel, expenses for testing and laboratory facilities and depreciation on property, plant and equipment used solely for research and development activities. Such costs are charged to the operations as we incur them. The increase in the latest fiscal year is primarily attributable to an increase in our expenditures on the research and development of the drug delivery platform and preparations for the undertaking of clinical trials relating to pancreatic application of BrachySil.

For a more detailed discussion of our research and development activities and policies, please see Item 4B, "Business Overview".

# **D. TREND INFORMATION**

As we are a development stage enterprise, it is not possible for us to predict with any degree of accuracy the outcome of the research and commercialization efforts being undertaken.

As in prior periods, expenditure on research and development, as a proportion of total costs, is expected to be significant and increase from the A\$8.3 million spent during the year ended June 30, 2005, unless cutbacks are required to conserve cash. Prior to completing the acquisition of CDS on December 30, 2005, we expected that research and development expenditure during the year ending June 30, 2006 would be approximately A\$13.5 million as we continued with the clinical trials in Singapore of BrachySil and expected to undertake additional work on other applications of BioSilicon, including targeted in situ cancer treatments. Following the acquisition of CDS, however, it is expected that this pre-acquisition estimate will increase significantly. However, we expect to continue to fund this expense from existing cash balances in the near future.

Our recent acquisition of CDS will have profound effects on the nature of our business and operations as a whole and we expect that therefore our current reported financial information may not be indicative of our future results or financial condition. For a description of the acquisition, see Item 8B, "Significant Changes".

### E. OFF-BALANCE SHEET ARRANGEMENTS

We currently do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

## F. CONTRACTUAL OBLIGATIONS TABULAR DISCLOSURE

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

		Payments Due by Period (In thousands of Australian Dollars)			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual Obligations					
Long-Term Debt Obligations		_	—	—	—
Capital (Finance) Lease Obligations	—		_		
Operating Lease Obligations	448	326	122	—	—
Purchase Obligations	—	—	—	—	—
Other Long-Term Liabilities	—		—	—	—
Total	448	326	122		
	57				

# ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

# A. DIRECTORS AND SENIOR MANAGEMENT

# pSivida

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

Name	Date of Appointment	Principal Occupation
Dr. Roger Brimblecombe	March 5, 2002	Independent Consultant
Dr. Roger Aston (1)	December 1, 2000	Independent Consultant
Mr. Gavin Rezos	December 1, 2000	Managing Director, pSivida Limited
Ms. Alison Ledger (2)	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. Paul Ashton	December 30, 2005	Executive Director of Strategy, pSivida Limited and Interim President, pSivida Inc.
Ms. Heather Zampatti	January 11, 2006	Non-Executive Director, pSivida Limited; Head of Wealth Management Australia, Bell Potter Securities

(1) Dr. Aston resigned from pSivida's board on November 15, 2005.

(2) Ms. Ledger resigned from pSivida's board on January 11, 2006.

# 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.), and a non-executive director of Vertex Pharmaceuticals Inc (U.S.A), Vertex Pharmaceuticals (Europe) Ltd and Tissue Science Laboratories Ltd. He has provided strategic consultancy services to research and development companies in Europe, the U.S. and Japan. He is a fellow of the 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, and a director of pSivida Inc.

# 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, pSiNutria and AiMedics Pty Ltd (Australia) and nonexecutive chairman of AION Diagnostics and pSivida Inc.

# 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. Ms. Ledger resigned as a director of pSivida on January 11, 2006.

# 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 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 Avanir Pharmaceuticals (appointed 1 August 2005).

# Michael Rogers

Mr. 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."

### Dr. Paul Ashton

Dr. Ashton was the President and Chief Executive Officer of CDS prior to its acquisition by pSivida on December 30, 2005. He co-founded CDS in 1991 and since then has served as a director of CDS, becoming President and Chief Executive Officer in 1996. As a scientist, Dr. Ashton is internationally renowned in the field of



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ocular drug delivery and is one of the inventors of Vitrasert<sup>®</sup> and Retisert<sup>TM</sup>, two CDS products approved by the FDA. He has authored over 200 papers and abstracts, holds more than 25 patents and has more than 150 pending patent applications. Dr. Ashton received a Bachelor of Science in Chemistry from Durham University, England and a PhD in pharmaceutical science for the University of Wales.

#### Heather Zampatti

Ms. Zampatti, BSc, DipEd, is Head of Wealth Management, Australia, for Bell Potter Securities and has over 20 years' experience in investment advising, specializing in stockbrokerage and financial investment planning. Ms. Zampatti holds board positions on the Princess Margaret Hospital for Children Foundation, the Australian Institute of Management (Western Australia) and Osteoporosis Australia. Ms. Zampatti holds a Bachelor of Science and a Diploma of Education from the University of Western Australia and is a Certified Financial Planner.

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:

Name	Title
Mr. Gavin Rezos	Managing Director, pSivida Limited
Mr. Aaron Finlay	Chief Financial Officer and Company Secretary, pSivida Limited
Dr. Anna Kluczewska	Managing Director, AION Diagnostics
Dr. Paul Ashton	Executive Director of Strategy, pSivida Limited and Interim President, pSivida Inc.
Mr. Michael Soja	Vice President of Finance, Chief Financial Officer and Treasurer, pSivida Inc.
Ms. Lori Freedman	Vice President for Corporate Affairs, General Counsel and Secretary, pSivida Inc.

## 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 Kluczewska

Dr. Kluczewska 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. Kluczewska is also Managing Director of AION Diagnostics.

# Michael Soja

Mr. Soja has served as CDS' Vice President of Finance and Chief Financial Officer since 2001. From 1974 to 2001, Mr. Soja was employed by XTRA Corporation, a lessor of transportation equipment, serving as Vice President and Chief Financial Officer from 1980 to 2001. Mr. Soja received a B.A. in Mathematics from the College of the Holy Cross in 1970, an M.S. in Accounting from Northeastern University in 1971 and an M.B.A. from Babson College in 1978.



# Lori Freedman

Ms. Freedman has served as CDS' Vice President of Corporate Affairs, General Counsel, and Secretary since 2001. From March 2001 through September 2001, Ms. Freedman served as Vice President, Business Development, and Counsel of Macromedia, Inc., a provider of software for creating Internet content and business applications. Ms. Freedman served as Vice President, General Counsel, and Secretary of Allaire Corporation, a provider of Internet infrastructure for building business applications, from 1999 until Allaire was acquired by Macromedia in 2001. From May 1998 to December 1998, Ms. Freedman worked for Polaroid Corporation as a Corporate Counsel. Prior to joining Polaroid, Ms. Freedman was with the law firm of McDermott, Will & Emery. Ms. Freedman received a B.S. in Economics and Psychology from Brandeis University and a J.D. from Boston University.

### pSivida Inc.

On December 30, 2005, pSivida acquired all of the capital stock of Control Delivery Systems, Inc., which was renamed pSivida Inc. The members of the board of directors of pSivida Inc. and their principal occupations are as follows:

Name	Principal Occupation
Mr. Gavin Rezos	Managing Director, pSivida Limited
Mr. Roger Brimblecombe	Independent Consultant
Dr. Paul Ashton	Interim President of pSivida Inc. and Executive Director of Strategy, pSivida Limited
Mr. Michael Soja	Vice President of Finance, Chief Financial Officer and Treasurer, pSivida Inc.
Ms. Lori Freedman	Vice President for Corporate Affairs, General Counsel and Secretary, pSivida Inc.

The executive officers of pSivida Inc. and their principal occupations are as follows:

Name	Title
Mr. Gavin Rezos	Chairman
Dr. Paul Ashton	Interim President
Mr. Michael Soja	Vice President of Finance, Chief Financial Officer and Treasurer
Ms. Lori Freedman	Vice President for Corporate Affairs, General Counsel and Secretary

# pSiMedica Limited

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

Name	Principal Occupation
Dr. Roger Brimblecombe	Independent Consultant
Mr. Gavin Rezos	Managing Director, pSivida Limited
Prof. Leigh Canham	Chief Scientific Officer, pSiMedica
Dr. Mark Parry-Billings	Research & Development Director, pSiMedica

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

Name	Title
Prof. Leigh Canham	Chief Scientific Officer
Dr. Mark Parry-Billings	Research and Development Director
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.

### 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 Defence 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:

Name	Principal Occupation		
Dr. Roger Brimblecombe	Independent Consultant		
Mr. Gavin Rezos	Managing Director, pSivida Limited		
Dr. Beng Choo Lim	Clinical Director, pSiOncology Pte Ltd		
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 nasopharyngeal cancer, vitreous hemorrhage, Hepatitis B, peptic ulcer, respiratory, dermatology and anti-infectives.

The executive officer of pSiOncology and her title is as follows:

Name Dr. Beng Choo Lim

Clinical Project Manager

# **AION Diagnostics Limited**

Wholly-owned subsidiary AION Diagnostics Limited appointed Dr Jörg 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:

Title

Name	Principal Occupation			
Mr. Gavin Rezos	Managing Director, pSivida			
Prof. Leigh Canham	Chief Scientific Officer, pSiMedica; Director, AION Diagnostics			
Dr. Anna Kluczewska	Head of Diagnostics, pSivida; Managing Director, AION Diagnostics			
Dr. Jörg Schreiber PhD	Non-executive Director			
The executive officers of AION Diagnostics and their titles are as follows:				

Title

Name Dr. Anna Kluczewska Mr. Aaron Finlay

Managing Director Chief Financial Officer and Company Secretary

# pSiNutria Limited

Wholly-owned subsidiary pSiNutria was incorporated on December 5, 2005. The members of the Board of Directors of pSiNutria and their principal occupations are as follows:

Name	Principal Occupation			
Mr. Gavin Rezos	Managing Director, pSivida Limited			
Prof. Leigh Canham	Chief Scientific Officer, pSiMedica; Director, AION Diagnostics			
Mr. Stephen Lake	Investment Director, QinetiQ			
Mr. Aaron Finlay	Chief Financial Officer and Company Secretary, pSivida Limited			

# **B. 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 our executive directors are formalized in a service agreement. Details of the nature and amount of each element of the emoluments of each of our directors for the financial year are shown in the following table. The following table presents all compensation paid to our directors and executive management for the year ended June 30, 2005.

	Primary		Post			
	Salary and Fees S	Bonus S	Employment Superannuation S	Other Benefits S	Equity Options S	<u> </u>
Specified directors						
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
Specified executives(1)						
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 Kluczewska	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 were the five highest paid executives of pSivida for the year ended June 30, 2005, 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\$0.46 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 our annual general meeting held on November 15, 2005) and executives on April 22, 2005 and have values ranging between A\$0.30 and A\$0.34 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.

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We have 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, we are 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. We make 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.

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.

# C. BOARD PRACTICES

The business of pSivida is managed by its directors. The directors exercise all of the powers that our constitution, the Corporations Act 2001, the Australian Stock Exchange or the Australian Stock Exchange 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 our strategic direction;
- identifying the expectations of our 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 our 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 our 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;
- 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.

Our 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, our constitution permits the election of a director at general meeting and by ordinary resolution. 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 the company 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 one director is 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 re-elected at a general meeting by ordinary resolution on October 21, 2003 and did not stand for re-election at pSivida's most recent Annual General Meeting held on November 15, 2005. 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 re-elected at our annual general meeting held on November 15, 2005. Ms. Ledger resigned as a director on January 11, 2006, and the board appointed Ms. Zampatti as a director on the same date.

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.

Our 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, our constitution permits:

- members by ordinary resolution; or
- members holding a majority of our issued, voting shares by written notice to the company,

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, shareholder approvals and other matters.

# 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 the company 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 us since July 31, 2005. We have taken appropriate steps with respect to our corporate governance system so that our 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 we are listed on NASDAQ and rules applicable to us so require:

- we will continue to have a board of directors consisting of a majority of independent directors, as defined under NASDAQ's corporate governance rules;
- we 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 our financial statements or any of our 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.

- we 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.
- we 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.
- we will either ensure that our 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 our independent directors.
- we 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.
- we will hold regularly scheduled meetings at which only independent directors are present.

We have 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 1/3% of the outstanding shares of a company's common voting stock. Our constitution provides for a quorum requirement of two members at general meetings of our shareholders. This quorum requirement is in accordance with Australian law and generally accepted business practices in Australia.

# Independence of Directors

During her tenure as a director of pSivida, the board of directors considered Ms. Ledger to be an independent director. She had an indirect interest in 1,900,000 ordinary shares held by her spouse representing 0.49% of the outstanding ordinary shares as of December 31, 2005. Ms. Ledger resigned from the board on January 11, 2006 and Ms. Zampatti was appointed to the board on the same date. The board considers Ms. Zampatti to be an independent director. She currently holds no shares or options of pSivida.

The board of directors considers Messrs. Mazzo and Rogers to be independent directors. We have 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 is currently our largest shareholder, holding approximately 9.22% of our issued share capital at December 31, 2005. The board does not consider that QinetiQ's shareholding affects Mr. Lake's independence on the basis that QinetiQ has sufficient and suitably documented policies and procedures in place 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 our strategic direction, and report the outcome of that assessment to the board;
- 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 our 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 consider 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 14, 2005, the members of the nomination committee were Dr. Brimblecombe (Chairperson); Ms. Ledger and Dr. Aston. Since November 14, 2005 the members of the nomination committee have been Dr. Brimblecombe (Chairperson) and Mr. Rezos.

#### **Remuneration Committee**

The role of the remuneration committee is to assist the board in ensuring that appropriate and effective remuneration packages and policies for the Managing Director and executive directors are implemented within our company 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 our company and its subsidiaries;
- review and recommend to the board proposals for employee and non-executive director equity plans;
- review and recommend to the board proposals for short and long term incentive programs for the Managing Director and executive directors;
- review and recommend to the 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.

The decisions of the committee, as contained in its minutes, shall constitute recommendations to the board. The 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 our 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, our chief executive officer may not be present during voting or deliberations. Compensation of all other executive officers will also 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.

The remuneration committee is comprised of at least two members of the board. From August 2, 2004 until November 15, 2005, and the member of the renumeration committee were Dr. Brimblecombe (Chairman), 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

The 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 process of the company and the audits of the company's financial statements.

The audit and compliance committee is particularly concerned with audit compliance amongst our company and its subsidiaries.

The audit and compliance committee is directly responsible to 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 the 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 our 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;
- establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls, or auditing matters, and the confidential, anonymous submission by our employees of concern regarding questionable accounting or auditing maters;
- taking action with respect to any other business processes or functions that may be referred to it by the board; and
- ensuring its receipt from the outside auditors of a formal written statement delineating all relationships between the auditor and the company, 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 the board.

The audit and compliance committee is directly responsible for making recommendations to the board on 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.

The 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. The audit and compliance committee may delegate 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. Our 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 the board.

When reviewing the independence of the external auditor the committee will encourage the rotation of the audit partner at least once every five years.

The audit and compliance committee is comprised of at least three members of the board. The members of our audit and compliance committee shall meet the independence and experience requirements of the SEC and NASDAQ. At least one of the members of our 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. From August 2, 2004 to July 28, 2005 the members of the audit and compliance committee were Ms. Ledger (Chair), Dr. Brimblecombe and Mr. Lake. From July 28, 2005 to January 11, 2006 the members of the audit and compliance committee were Mr. Rogers (Chair), Ms. Ledger and Dr. Mazzo. As of January 11, 2006 the members of pSivida's audit and compliance committee are Mr. Rogers (Chair), Dr. Mazzo and Ms. Zampatti. Since July 28, 2005, the committee's financial expert has been Mr. Rogers.

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

#### **Conduct and Ethics**

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

- compliance with the law;
- financial records;
- contributions to political parties, candidates and campaigns;
- occupational health and safety;
- 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, we have adopted separate corporate governance policies relating to insider trading, continuous disclosure, communications strategy and risk management. Summaries of these policies are available on our corporate website, and we make the full policies available to the public upon request. We believe that our continuous disclosure policy and our 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 our corporate website. In addition, we file with the SEC on Form 6-K a copy of each release which we file with the ASX and post on our corporate website.

### Shareholder Approval of Share Issuance

The issuance of securities by us is subject to the shareholder approval requirements of the ASX Listing Rules and the NASDAQ Marketplace Rules. ASX Listing Rule 7.1 states that a company may not issue securities amounting to more than 15% of such company's issued share capital in any 12 month period without obtaining shareholder approval. Rule 4350(i)(1) of the NASDAQ Marketplace Rules states that an issuer must obtain shareholder approval in order to issue securities in certain transactions, including issuances in connection with a transaction (other than a public offering) of securities having 20% or more of the voting power outstanding before the issuance. NASDAQ Marketplace Rules permit a foreign private issuer to follow its home country practice in lieu of the requirements of Rule 4350. A foreign private issuer that follows a home country practice in lieu of one or more provisions of Rule 4350 must disclose each requirement of Rule 4350 that it does not follow and describe the home country practice followed by the issuer in lieu of such requirements.

In obtaining shareholder approval for the issuance of shares underlying the convertible note entered into by us on November 16, 2005, we obtained shareholder approval pursuant to our home country practice as embodied in ASX Listing Rule 7.1, and while the issuance of the shares was approved, we may not have received shareholder approval under NASDAQ Marketplace Rule 4350(i)(1), as we did not specifically request approval under that rule.

### **D. EMPLOYEES**

As of June 30, 2005, we had 36 employees, excluding directors and consultants. Of such employees, 20 were employed in research and development and 16 in management and administration; 19 employees were located in Malvern, United Kingdom, 4 in Singapore and 13 in Perth, Western Australia.

On December 30, 2005, we completed the acquisition of Control Delivery Systems, Inc., which has been renamed pSivida Inc. As a result of the acquisition, as of December 31, 2005 we have 12 employees located in Boston, U.S.A.

Australian, UK, Singaporean and US labor laws and regulations are applicable to all of our 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.

### **E. SHARE OWNERSHIP**

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

The following table sets forth certain information as of December 31, 2005 regarding the beneficial ownership by each of our directors and executive officers:

Ontions in

Directors and Executive Officers of pSivida Limited

	Ordinary Shares		Ор	Options		Subsidiary (19)		
	Held Directly	Held Indirectly	Held Directly	Held Indirectly	Total Share Ownership (3)	Held Directly	Held Indirectly	
R. Brimblecombe (8)	445,067		1,324,111		*			
G J Rezos (4), (7)	2,018,630	9,272,652	3,371,030	1,800,000	4.05%	_	250,000	
S Lake	_	—	242,061	_	*	_		
A Ledger	—	1,900,000		200,000	*	_		
D Mazzo	_	—	200,000	_	*	_		
M Rogers	_	—	200,000	_	*	_		
P Ashton (5), (9)	16,992,810	671,270	1,380,700		4.78%	_		
A Finlay (10)	_	—	—	1,100,000	*	_	108,760	
A Kluczewska (11)	—	—	1,425,000		*	495,040		
L Freedman (12)	2,786,320	—	237,500	_	*	_		
M Soja (13)	3,060,460	—	237,500		*	—	—	
	25,303,287	11,843,922	8,617,902	3,100,000	11.68%	495,040	358,760	

#### Other pSivida Group Executive Officers

	Ordinary Shares		Opt	Options		Options in Subsidiary (19)	
	Held Directly	Held Indirectly	Held Directly	Held Indirectly	Total Share Ownership (3)	Held Directly	Held Indirectly
R Aston (6), (14)	5,618,586	1,475,000	1,049,111	500,000	2.22%		
L Canham (15)	3,730,000	_	864,289	_	1.15%	_	110,840
M Parry-Billings (16)	_	_	1,200,000	_	*	_	
J Ogden (17)	_	_	554,708	_	*	_	
S Connor (18)		189,000	444,645		*		
	9,348,586	1,664,000	4,112,753	500,000	3.70%	_	110,840
	34,651,873	13,507,922	12,730,655	3,600,000	15.20%	495,040	469,600
			73				

- \* These Executive Officers and Directors hold less than 1% of our outstanding capital stock.
- (1) The percentages are based on 387,009,956 ordinary shares issued and outstanding as at December 31, 2005.
- (2) 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 annual report 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.
- (3) For the purposes of calculating total share ownership, the number of ordinary shares held includes shares issuable upon the exercise of options that are exercisable or will become exercisable within 60 days of December 31, 2005 for the following individuals: Dr. Brimblecombe (1,024,111 shares), Mr. Rezos (4,571,030 shares), Mr. Lake (242,061 shares), Ms. Ledger (200,000 shares), Dr. Ashton (880,700 shares), Mr. Finlay (900,000 shares), Dr. Kluczewska (1,300,000 shares), Dr. Ashton (1,549,111 shares), Prof. Canham (739,289 shares), Dr. Parry-Billings (400,000 shares), Dr. Ogden (439,708 shares) and Mr. Connor (319,645 shares).
- (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 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.
- (5) Of such shares, 16,992,810 are held directly by Dr. Ashton and 671,270 are held by Paul Ashton Children's Irrevocable Trust as to which Dr. Ashton disclaims beneficial ownership.
- (6) 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.
- (7) 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; 1,200,000 are held by Aymon Pacific Pty Ltd as trustee for the Jerezos Discretionary Trust 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; 600,000 are held directly by Mr. Rezos 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; 600,000 are held directly by Mr. Rezos 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; and 600,000 are held by Mrs. Joanne Rezos available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on September 30, 2010.
- (8) 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; 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; 300,000 are held directly by Dr. Brimblecombe available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on March 31, 2010; and 75,000 are held directly by Dr. Brimblecombe available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on March 31, 2010; and 75,000 are held directly by Dr. Brimblecombe available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on March 31, 2010; and 75,000 are held directly by Dr. Brimblecombe available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on March 31, 2010; and 75,000 are held directly by Dr. Brimblecombe available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.92 per share expiring on September 30, 2010.
- (9) Of such options, 352,280 are held directly by Dr. Ashton and available to be exercised into an equal number of ordinary shares with an exercise price of US\$0.22709 per share expiring on August 25, 2009; 528,420 are held directly by Dr. Ashton available to be exercised into an equal number of ordinary shares with an exercise price of US\$0.17742 per share expiring on September 18, 2007; and 500,000 are held directly by Dr. Ashton available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.92 per share expiring on September 30, 2010.

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- (10) 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; 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; 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; 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\$0.92 per share expiring on September 30, 2010.
- (11) Of such options, 1,200,000 are held directly by Dr Kluczewska 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 Kluczewska 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 Kluczewska available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on 31 March 2010.
- (12) Of such options, 237,500 are held directly by Ms. Freedman available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.92 per share expiring on September 30, 2010.
- (13) Of such options, 237,500 are held directly by Mr. Soja available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.92 per share expiring on September 30, 2010.
- (14) 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; 549,111 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 500,000 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, available to be the beneficial owner of the options held directly by Insinger (Trust) Jersey Ltd and Newtonmore Biosciences Pty Ltd.
- (15) 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 and 125,000 are held directly by Prof Canham available to be exercised into an equal number of ordinary shares with an exercise price of A\$0.80 per share expiring on 31 March 2010.
- (16) 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 on 31 March 2010.
- (17) 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 on 31 March 2010.
- (18) 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 on 31 March 2010.
- (19) 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 our 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 with performance guidelines established by the board of directors of pSivida. The following table presents option grant information as of December 31, 2005.

Options outstanding 31,169,162\* Weighted Average exercise price A\$1.00

\* Note that 11,442,490 of these options were not issued under the ESOP.

## Plan Administration

The ESOP is administered by pSivida's board.

## ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### A. MAJOR SHAREHOLDERS

The following table sets forth certain information as at December 31, 2005, regarding the beneficial ownership by all shareholders known to us to own beneficially 5% or more of pSivida's ordinary shares, including shares held by means of ADSs. The voting rights of our major shareholders do not differ from the voting rights of other holders of its ordinary shares.

	Number of	Percentage of
	Ordinary Shares	Outstanding
	Beneficially	Ordinary
Shareholder	Owned(1)	Shares(2)
QinetiQ Group Plc	35,699,629(3)	9.22%
Bausch & Lomb Incorporated	21,136,940(4)	5.5%

<sup>(1)</sup> Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes 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 annual report 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 387,009,956 ordinary shares issued and outstanding as at December 31, 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 GU14 OLX, United Kingdom.
- (4) Held in the form of ADSs, each of which represents 10 ordinary shares.

As of December 31, 2005, we had 387,009,956 ordinary shares on issue, of which 129,314,638 were held by 3,557 Australian resident holders and 257,695,318 were held by 774 foreign holders. Of the foreign holders, 624 representing 167,279,360 ordinary shares, or 43.2%, are known by us to have U.S. addresses at December 31, 2005.

As of December 31, 2005, we had 31,169,162 options convertible into ordinary shares on issue, of which 11,115,141 were held by 15 Australian resident holders and 20,054,021 were held by 56 foreign holders. Thirty-two of the foreign holders, representing 13,132,490 options, are known by us to have U.S. addresses as of December 31, 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 our 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 our shareholders. The deed poll can be enforced by any of our 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.

We are 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. We do not know of any arrangements, the operation of which may at a subsequent date result in a change in control of pSivida.

## **B. RELATED PARTY TRANSACTIONS**

During the years ended June 30, 2005, 2004 and 2003, we 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 for the use of laboratory facilities and for patent filing and administration. Amounts of £32,491 (approximately A\$76,324) were paid during the period from July 1 to December 31 of 2005. 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. By December 31, 2004, QinetiQ's ownership interest in pSivida was reduced to 9.22%, principally as a result of the December 30, 2005 acquisition of CDS.

During the years ended June 30, 2005, 2004 and 2003 we 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. Amounts of A\$148,317 were paid during the period from July 1 to December 31 of 2005.

During the years ended June 30, 2005, 2004 and 2003, we 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, we paid amounts of Nil, A\$12,367 and A\$52,187, respectively, to Viaticus Capital Pty Ltd, a company controlled by Mr. Rezos, for sublease of BGC Centre office space. In addition, amounts of A\$438,556 were paid during the period from July 1 to December 31 of 2005 for consulting services provided by Mr. Rezos.

During the years ended June 30, 2005, 2004 and 2003, we paid Blake Dawson Waldron A\$114,832, A\$78,068 and A\$22,622, respectively, for various routine armslength legal services. Blake Dawson Waldron is a national Australian law firm, and one of the partners thereof is a relative of a pSivida director. Amounts of A\$178,568 were paid during the period from July 1 to December 31 of 2005.

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. Amounts of A\$165,220 were paid to Albion Capital during the period from July 1 to December 31 of 2005 for the sublease of BCG Centre office space and for financial analysis and accounting services.

During the year ended June 30, 2005, CDS (now pSivida Inc.) revised a license agreement with Bausch & Lomb Incorporated, a large shareholder in CDS. CDS received an immediate payment of US\$3 million (A\$4.1 million) from Bausch & Lomb in exchange for the right to receive future royalties in the amount of US\$6.25 million (A\$8.6 million) otherwise payable under the original license agreement. Upon pSivida's acquisition of CDS in December 30, 2005, Bausch & Lomb became the holder of 5.5% of pSivida's outstanding capital stock. The license agreement was not affected by the acquisition and remains in full force and effect.

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.

# C. INTERESTS OF EXPERTS AND COUNSEL

Not applicable.

# **ITEM 8. FINANCIAL INFORMATION**

# A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION

See Item 18, "Financial Statements".

## Legal Proceedings

A potential lender to pSivida Inc. (formerly CDS) has claimed a break-up fee as a result of the royalty advance agreement between pSivida Inc. and Bausch & Lomb Incorporated. An investment banker has claimed an advisory fee in connection with that agreement as well as the acquisition of CDS by pSivida. We intend to defend against these claims.

## **Dividend Distribution Pending**

We currently intend to retain any future earnings to finance the growth, development and expansion of our business. Accordingly, we do 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 our board of directors after taking into account various factors, including our 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.

# **B. SIGNIFICANT CHANGES**

## Private Investment in Public Equity

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

## Acquisition of CDS

### The Merger

On October 3, 2005, we entered into a merger agreement with CDS, a Boston-based company engaged in the design and development of drug delivery products. The merger agreement provided that a newly-formed subsidiary of pSivida would merge into CDS, with CDS surviving the merger as a wholly-owned subsidiary of pSivida with the name of pSivida Inc. After approval by the required majorities of both companies' shareholders and the fulfillment of other closing conditions, the merger was completed on December 30, 2005.

### Consideration

In exchange for their CDS shares, the former stockholders of CDS received 15,983,661 of our ADSs. Based on a price of A\$0.71 per share, the price prevailing upon the closing of the merger, the transaction represents a purchase price of approximately A\$118.8 million (US\$86.7 million). As of December 31, 2005, the ADSs received by the former CDS stockholders represented approximately 41.3% of the capital stock of the combined company. Certain former shareholders of CDS received cash rather than ADSs for their CDS shares. The total amount of such cash, which depended on the market value, on or about the date of the merger, of the ADSs that such shareholders would have received in the merger, was US\$83,116. In addition, each outstanding option to purchase CDS stock was assumed by us and effectively converted into an option to acquire such number of ADSs as the holder would have been entitled to receive in the merger if such holder had exercised such option in full immediately before completion of the merger.

## Restricted ADSs; Registration Rights Agreement

The ADSs issued to the former CDS stockholders in the merger have not been registered under the Securities Act, but have been issued in a private placement conducted in accordance with Section 4(2) of the Securities Act and Regulation D thereunder. Accordingly, such ADSs may not be sold unless registered with the SEC for resale or sold in a transaction exempt from registration under the Securities Act. We have agreed to register the resale of the ADSs issued to the former CDS stockholders who have entered into a registration rights agreement with us and, among other things, have agreed not to transfer or sell their ADSs for the six months following the closing of the merger (subject to certain exceptions).

#### Interests of Officers of CDS in the Merger

Certain executive officers of CDS are expected to be employed by us in various capacities. Dr. Paul Ashton, recently President and Chief Executive Officer of CDS, will be appointed to the board of directors of pSivida and will serve as Executive Director of Strategy and Head of Research and Development of Ophthalmology of pSivida as well as Interim President of CDS. We intend to make employment offers to each of Lori Freedman, the general counsel of CDS and Michael Soja, the chief financial officer of CDS. These offers are currently being discussed and negotiated, and there can be no assurance that we will reach agreement with all or any of Dr. Ashton, Ms. Freedman and Mr. Soja regarding their employment relationship with the combined company.

#### **Business of the former CDS**

CDS, now renamed pSivida Inc., 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 pSivida Inc.'s target diseases: adverse side effects characteristic of high dosing levels and reduced treatment benefits due to variations in drug levels at the target site.

pSivida Inc. has two commercial products utilizing the AEON system approved by the 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, the third leading cause of blindness in the U.S. Bausch & Lomb is also conducting two long-term multi-center clinical trials of Retisert for the treatment of DME, another leading cause of vision loss. Medidur, an injectable AEON product, is also designed to treat DME and is currently in fast-track Phase III clinical trials conducted by Alimera Sciences Inc. pSivida Inc. also has two AEON product candidates in pre-clinical studies for other back of the eye diseases. For a more detailed description of the business of pSivida Inc., see Item 4B "Business of Psivida Inc."

### License Agreement with Beijing Med-Pharm

On October 27, 2005 we signed a license with Beijing Med-Pharm Corporation for the clinical development, marketing and distribution of BrachySil in China. Under the terms of the license, we will manufacture BrachySil and Beijing Med-Pharm will be responsible for clinical development, securing regulatory approval, marketing and distribution in China. pSivida will retain manufacturing rights for BrachySil under the license. 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 payments to pSivida of US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the manufacturing and supply agreement, and additional payments of up to US\$1,750,000 (approximately A\$2,400,000) if certain milestones are achieved. In addition, we will receive royalties ranging from 10% up to 30%, depending upon level of sales.

**Convertible Note Financing** 

On November 16, 2005, we issued a subordinated convertible promissory note in the principal amount of US\$15 million (A\$19.7 million) to an institutional investor. The note will bear interest at a rate equal to 8% per annum, have a term of three years and a conversion price of US\$7.10, subject to adjustment based on certain events or circumstances, including the market price of ADSs for the ten trading days ending on May 5, 2006. We also issued a warrant with a term of six years which will entitle the investor to purchase 633,803 ADSs at US\$7.20 per ADS, subject to adjustment. We have also entered into a registration rights agreement pursuant to which we have agreed to file a registration statement covering the resale of the ADSs underlying the note and the warrant as soon as practicable and to have the registration statement declared effective within 180 days of issuance of the notes and warrants. The proceeds of the issuance are expected to be used for the expanded development of BioSilicon and for general corporate purposes.

## **ITEM 9. THE OFFER AND LISTING**

## A. OFFER AND LISTING DETAILS

Our ordinary shares were listed on the ASX in December 2000. The following table sets forth, for the periods indicated, the highest and lowest market quotations for the ordinary shares reported on the daily official list of the ASX.

Hig	gh	Low
	(i	in Australian dollars)
		0.85
		0.535
		0.75
0.9	94	0.55
0.8	375	0.75
0.9	945	0.815
0.9	90	0.80
0.9	94	0.72
0.7	79	0.55
0.7	75	0.58
1.4	14	0.52
1.3	34	1.03
1.1	6	0.90
1.4	43	1.02
0.2	21	0.155
0.2	275	0.16
0.6	59	0.23
0.7	70	0.51
0.2	265	0.225
0.2	245	0.155
0.1	75	0.135
0.2	215	0.10
0.4	10	0.30
0.3	335	0.21
0.2	27	0.09
0.3	34	0.11
	1.2 0.9 0.9 0.9 0.9 0.8 0.9 0.9 0.9 0.9 0.9 0.9 0.9 0.9 0.9 0.9	$\begin{array}{c} 2 \\ 1.25 \\ 0.935 \\ 0.945 \\ 0.94 \\ 0.875 \\ 0.945 \\ 0.90 \\ 0.90 \\ 0.94 \\ 0.79 \\ 0.75 \\ 1.44 \\ 1.34 \\ 1.16 \\ 1.43 \\ 0.21 \\ 0.275 \\ 0.69 \\ 0.70 \\ 0.265 \\ 0.245 \\ 0.175 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.215 \\ 0.27 \\ 0.25 \\ 0.27 \\ $

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

Calendar Year		High	Low
			(in Australian dollars)
2005	First quarter	12.14	6.30
	Second quarter	8.00	4.15

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Calendar Year	High	Low (in U.S. dollars)
Third quarter	8.75	5.60
Fourth Quarter	7.00	4.21
July	7.13	5.60
August	8.75	6.25
September	6.80	6.02
October	7.00	5.20
November	6.00	4.21
December	5.697	4.32

## **B. PLAN OF DISTRIBUTION**

Not applicable.

## C. MARKETS

Our primary listing is on the ASX, trading under the symbol "PSD". Since January, 2005 we have been listed in the NASDAQ National Market under the symbol "PSDV". In addition, we are also listed on the Frankfurt, Berlin, Munich and Stuttgart exchanges under the symbol "PSI". Our shares also trade in the United Kingdom on the OFEX International Market Service (IMS) under the symbol "PSD".

## D. SELLING SHAREHOLDERS

Not applicable.

## E. DILUTION

Not applicable.

### F. EXPENSES OF THE ISSUE

Not applicable.

## **ITEM 10. ADDITIONAL INFORMATION**

A. SHARE CAPITAL

Not applicable.

## **B. OUR CONSTITUTION**

This information is included in Item 10B of the registration statement filed by us on Form 20-F with the SEC on January 20, 2005, and is incorporated herein by reference.

### C. MATERIAL CONTRACTS

### AEA Technology QSA GmbH

During March 2004 pSiMedica entered into a three year agreement with AEA Technology QSA GmbH for the production and manufacture of radioactive 32P-BioSilicon nano-structured microparticles to meet pSiMedica's commercial supply requirements. Under the terms of the agreement we will be required to meet £870,000 (approximately A\$2.28 million) in project costs as part of the development phase to enable the production of 32P-BioSilicon. This cost relates to the acquisition of Hot Cells and production plant and equipment, the title of which will be transferred to us. This facility was completed in September 2005.

### Acquisition of pSiMedica Limited

On August 4, 2004, we completed the A\$57.8 million acquisition of the outside equity interest in shares of pSiMedica Ltd. The transactions entered into in order to affect the acquisition involved firstly the minority shareholders in pSiOncology exchanging their pSiOncology shares for newly issued shares in pSiMedica, such that pSiMedica now holds 100% of the issued share capital of pSiOncology. Subsequently, we acquired the balance of pSiMedica shares, namely those held by the QinetiQ group and other minority shareholders, including pSiMedica management, SGH Technology Ventures Pre Ltd and Biotech Research Ventures Pte Ltd. In consideration for the pSiMedica shares, we paid A\$4,323,622 in cash and issued an additional 49,804,381 ordinary shares at A\$1.09. In addition, we issued 678,537 options at an exercise price of A\$1.18 which expire on August 5, 2009 in relation to pSiMedica options previously granted to directors and employees of pSiMedica.

#### **Private Investment in Public Equity**

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

## Acquisition of CDS — Merger Agreement

On October 3, 2005, we entered into a merger agreement with CDS, a Boston-based company engaged in the design and development of drug delivery products. The merger agreement provided that a newly-formed subsidiary of pSivida would merge into CDS, with CDS surviving the merger as a wholly-owned subsidiary of pSivida with the name of pSivida Inc. After approval by the required majorities of both companies' shareholders and the fulfillment of other closing conditions, the merger was completed on December 30, 2005.

In exchange for their CDS shares, the former stockholders of CDS received 15,983,661 of our ADSs. Based on a price of A\$0.71 per share, the price prevailing upon the closing of the merger, the transaction represents a purchase price of approximately A\$118.8 million (US\$86.7 million). As of December 31, 2005, the ADSs received by the former CDS stockholders represented approximately 41.3% of the capital stock of the combined company. Certain former shareholders of CDS received cash rather than ADSs for their CDS shares. The total amount of such cash, which depended on the market value, on or about the date of the merger, of the ADSs that such shareholders would have received in the merger, was US\$83,116. In addition, each outstanding option to purchase CDS stock was assumed by us and effectively converted into an option to acquire such number of ADSs as the holder would have been entitled to receive in the merger if such holder had exercised such option in full immediately before completion of the merger.

#### License Agreement with Beijing Med-Pharm

On October 27, 2005 we signed a license with Beijing Med-Pharm Corporation for the clinical development, marketing and distribution of BrachySil in China. Under the terms of the license, we will manufacture BrachySil and Beijing Med-Pharm will be responsible for clinical development, securing regulatory approval, marketing and distribution in China. pSivida will retain manufacturing rights for BrachySil under the license. 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 payments to pSivida of US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the license and US\$375,000 (approximately A\$514,000) upon entering into the manufacturing and supply agreement, and additional payments of up to US\$1,750,000 (approximately A\$2,400,000) if certain milestones are achieved. In addition, we will receive royalties ranging from 10% up to 30%, depending upon level of sales.

#### **Convertible Note Financing**

On November 16, 2005, we issued a subordinated convertible promissory note in the principal amount of US\$15 million (A\$19.7 million) to an institutional investor. The note will bear interest at a rate equal to 8% per annum, have a term of three years and a conversion price of US\$7.10, subject to adjustment based on certain events or circumstances, including the market price of ADSs for the ten trading days ending on May 5, 2006. We also issued a warrant with a term of six years which will entitle the investor to purchase 633,803 ADSs at US\$7.20 per

ADS, subject to adjustment. We have also entered into a registration rights agreement pursuant to which we have agreed to file a registration statement covering the resale of the ADSs underlying the note and the warrant as soon as practicable and to have the registration statement declared effective within 180 days of issuance of the notes and warrants. The proceeds of the issuance are expected to be used for the expanded development of BioSilicon and for general corporate purposes.

### **D. EXCHANGE CONTROLS**

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital, or similar funds belonging to foreign investors, except that certain payments to non-residents must be reported to the Australian Cash Transaction Reports Agency, which monitors such transactions.

#### The Foreign Acquisitions and Takeovers Act 1975

Under Australian law, foreign persons are prohibited from acquiring more than a limited percentage of the shares in an Australian company without approval from the Australian Federal Treasurer or in certain other limited circumstances. These limitations are set forth in the Australian Foreign Acquisitions and Takeovers Act 1975, or the Foreign Takeovers Act.

Under the Foreign Takeovers Act, as currently in effect, any foreign person, together with associates, is prohibited from acquiring 15% or more of our outstanding shares (or else the Australian Federal Treasurer may make an order requiring acquirer to dispose of those shares within a specified period of time). In addition, if a foreign person acquires shares in our company and as a result the total holdings of all foreign persons and their associates exceeds 40% in aggregate without the approval of the Australian Federal Treasurer may make an order requiring the acquirer to dispose of those shares within a specified time. Under the current Australian foreign investment policy, however, it is unlikely that the Treasurer would make such an order where the level of foreign ownership exceeds 40% in the ordinary course of trading, unless the Treasurer finds that the acquisition is contrary to the national interest. The same rule applies if the total holdings of all foreign persons and their associates already exceeds 40% and a foreign person (or its associate) acquires any further shares, including in the course of trading in the secondary market of the ADRs.

As stated above, the Australia-United States Free Trade Agreement has resulted in amendments being made to the Foreign Acquisitions and Takeovers Act regulations in Australia. The amendments provide that from January 1, 2005 the need for the Australian Federal Treasurer's approval will, in relation to acquisitions of interests in Australian shares by U.S. investors, only be required in relation to Australian companies with assets of more than A\$800 million. The approval process for non-U.S. investors will continue to be triggered by the current asset threshold of A\$50 million. The application of the A\$800 million threshold is subject to certain criteria including (but not limited to) the nature and residency of the U.S. investor.

If the level of foreign ownership exceeds 15% (for a single foreign person and their associates) (which is currently the case on the basis of the QinetiQ Group's holdings), or 40% (in aggregate for more than one foreign person and their associates) at any time, we would be considered a foreign person under the Foreign Takeovers Act. As such, we would be required to obtain the approval of the Australian Federal Treasurer, together with our associates, to acquire; (i) more than 15% of an Australian company or business with assets totaling over A\$50 million; or (ii) any direct or indirect ownership interest in Australian residential real estate.

The percentage of foreign ownership in our company would also be included in determining the foreign ownership of any Australian company or business in which it may choose to invest. Since we have no current plans for any such acquisitions and do not own any property, any such approvals required to be obtained by us as a foreign person under the Takeovers Act will not affect our current or future ownership or lease of property in Australia.

Our constitution does not contain any additional limitations on a non-resident's right to hold or vote our securities.

## **Corporations Act 2001**

As applied to us, the Corporations Act 2001 prohibits any legal person (including a corporation) from acquiring a relevant interest in Ordinary Shares if after the acquisition that person or any other person's voting power in pSivida increases from 20% or below to more than 20%, or from a starting point that is above 20% and below 90%.

This prohibition is subject to a number of specific exceptions set out in section 611 of the Corporations Act 2001 which must be strictly complied with to be applicable.

In general terms, a person is considered to have a "relevant interest" in a share in pSivida if that person is the holder of that share, has the power to exercise, or control the exercise of, a right to vote attached to that share, or has the power to dispose of, or to control the exercise of a power to dispose of that share.

It does not matter how remote the relevant interest is or how it arises. The concepts of "power" and "control" are given wide and extended meanings in this context in order to deem certain persons to hold a relevant interest. For example each person who has voting power above 20% in a company or a managed investment scheme which in turn holds shares in pSivida is deemed to have a relevant interest in those pSivida shares. Certain situations (set out in section 609 of the Corporations Act 2001) which would otherwise constitute the holding of a relevant interest are excluded from the definition.

A person's voting power in pSivida is that percentage of the total votes attached to Ordinary Shares in which that person and its associates (as defined in the Corporations Act 2001) holds a relevant interest.

#### E. TAXATION

The following is a summary of the material U.S. federal income tax and Australian tax consequences to U.S. holders, as defined below, of the acquisition, ownership and disposition of ADSs, or ordinary shares and is based on the laws in force as at the date of this annual report. Holders are advised to consult their tax advisers concerning the overall tax consequences of the acquisition, ownership and disposition of ADSs or ordinary shares in their particular circumstances. This discussion relies in part on representations by the deposit agreement and related documents and the assumption that each obligation in the deposit agreement and related documents will be performed in accordance with their terms.

### **Commonwealth of Australia Taxation**

### Dividends

Under the current double taxation convention between Australia and the U.S., dividends paid by us to a U.S. resident shareholder of pSivida, including a pSivida ADS holder, whose holding is not effectively connected with a permanent establishment in Australia or, in the case of a shareholder who performs independent personal services from a "fixed base' situated therein, is not connected with that "fixed base', may be subject to Australian withholding tax at a rate not exceeding 15% of such gross dividend. If the U.S. resident shareholder is a company which holds directly at least 10% of the voting power of pSivida, the withholding tax rate is limited to 5%.

Dividends paid to non-residents of Australia are exempt from withholding tax to the extent to which such dividends are "franked' under Australia's dividend imputation system or paid out of a foreign dividend account. Dividends are considered to be "franked' to the extent that they are paid out of post 1986-87 income on which Australian income tax has been levied. The foreign dividend account is an accumulation of dividends remitted to Australia by foreign subsidiaries. Any part of a dividend paid to a U.S. resident, which is not "franked' and is not paid out of a foreign dividend account, will generally be subject to Australian withholding tax unless a specific exemption applies.

### Sale of Ordinary Shares and ADSs

A U.S. citizen who is a resident of Australia, or a U.S. corporation that is a resident of Australia (by reason of carrying on business in Australia, and being managed or controlled in Australia, or having its voting power controlled by shareholders who are residents of Australia) may be liable for income tax on any profit on disposal of



ordinary shares or pSivida ADSs, or Australian capital gains tax on the disposal of ordinary shares or pSivida ADSs acquired after September 19, 1985.

Under Australian law as currently in effect, no income or other tax is payable on any profit on disposal of ordinary shares or pSivida ADSs held by persons not resident in Australia except if the profit is of an income nature and sourced in Australia, or the sale is subject to Australian capital gains tax.

The source of any profit on the disposal of ordinary shares or pSivida ADSs will depend on the factual circumstances of the actual disposal. Where the ordinary shares or pSivida ADSs are acquired and disposed of pursuant to contractual arrangements entered into and concluded outside Australia, and the seller and the purchaser are non-residents of Australia and do not have permanent establishments in Australia, the profit should not have an Australian source. If the profit is sourced in Australia, it will not be taxable in Australia if it represents business profits of an enterprise of the U.S. and the enterprise does not carry on business in Australia through a permanent establishment situated in Australia.

Any gain upon disposal of ordinary shares or pSivida ADSs, if held by a person not resident in Australia, may be subject to capital gains tax if the ordinary shares or pSivida ADSs have the "necessary connection with Australia". The ordinary shares or pSivida ADSs will have the necessary connection with Australia if the non-resident (together with associates, if any) beneficially owned at any time during the five years before the disposal, at least 10% by value of the shares of pSivida (excluding shares carrying no right to participate beyond a specified amount in a distribution of profits or capital). Ordinary shares or pSivida ADSs will also have the necessary connection with Australia if they have been used by the non-resident in carrying on a trade or business, wholly or partly, at or through a permanent establishment in Australia.

Australian capital gains tax is generally payable upon the profit arising from the sale of assets acquired after September 19, 1985. The profit is calculated as the disposal proceeds less the cost base. For assets acquired prior to September 19, 1999 and held for at least 12 months, the cost base can be indexed for inflation up to September 21, 1999. However, individuals can elect for only 50% of the profit (with no indexation) arising from the sale from assets acquired on or after 11:45 am Australian Eastern Standard Time September 21, 1999, to be subject to capital gains tax (provided the asset is held for at least 12 months). For assets acquired before September 21, 1999 but sold after September 21, 1999, individuals have the choice of calculating the capital gain as either 50% of the profit with no indexation or the disposal proceeds less the cost indexed for inflation up to September 30, 1999. Capital losses are not subject to indexation and can only be offset against capital gains.

#### Australian Stamp Duty

No Australian stamp duty will be payable on the acquisition of pSivida ADSs or on any subsequent transfer of a pSivida ADS, provided that the ADR evidencing such ADS remains at all times outside Australia, that the instrument of transfer is not executed in Australia and remains at all times outside Australia, and that the depositary maintains no register of pSivida ADSs, or any other securities, in Australia.

Any transfer of ordinary shares will not be subject to Australian stamp duty.

### **U.S. Federal Income Tax Considerations**

#### Material U.S. Federal Income Tax Consequences

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of pSivida's ADSs or ordinary shares by a beneficial owner of those ADSs or ordinary shares, referred to in each case for purposes of this discussion as a "U.S. Holder," that is:

- a citizen or individual resident of the United States;
- a corporation or other entity taxable as a corporation for U.S. federal income tax purposes that is created or organized in the United States or under the law of the United States or of any state or the District of Columbia;

- an estate whose income is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, if (1) a court within the United States is able to exercise primary supervision over the administration of the trust, and one or more United States persons have the authority to control all substantial decisions of the trust, or (2) the trust was in existence on August 20, 1996 and properly elected to continue to be treated as a United States person.

For U.S. federal income tax purposes, the beneficial owner of pSivida ADSs will be treated as the owner of the ordinary shares represented by the pSivida ADSs.

This summary does not purport to be a comprehensive description of all of the tax considerations that may be relevant to each U.S. Holder. This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, or the "Code", current and proposed Treasury Department regulations promulgated thereunder, judicial decisions and published positions of the U.S. Internal Revenue Service, referred to as the "IRS", and other applicable authorities, all as in effect as of the date of this annual report, and each of which is subject to change or to differing interpretations, possibly with retroactive effect. This discussion does not address all aspects of U.S. federal income taxation that may be relevant to any particular shareholder based on the shareholder's individual circumstances. In particular, this discussion considers only U.S. Holders that own pSivida's ADSs or ordinary shares as capital assets and does not address the potential application of the alternative minimum tax or the U.S. federal income tax consequences to U.S. Holders that are subject to special treatment, including, for example, U.S. Holders that:

- are broker-dealers or insurance companies;
- have elected mark-to-market accounting;
- are tax-exempt organizations;
- are financial institutions;
- hold pSivida ADSs or ordinary shares as part of a straddle, "hedge" or "conversion transaction" with other investments;
- acquired their pSivida ADSs or ordinary shares through the exercise of options or similar derivative securities or otherwise as compensation;
- have a functional currency that is not the U.S. dollar;
- are regulated investment companies, real estate investment trusts or financial asset securitization investment trusts; or
- persons who actually or constructively own ten percent or more of pSivida's ADSs or ordinary shares.

In addition, this discussion does not consider the tax treatment of persons who hold pSivida ADSs or ordinary shares through a partnership or other pass-through entity. This discussion does not address any aspect of state, local or non-U.S. tax laws or any U.S. federal tax laws other than U.S. federal income tax laws.

To ensure compliance imposed by the Internal Revenue Service, you are advised that the U.S. tax advice contained in this communication (i) is written in connection with the promotion or marketing of the transactions and matters addressed by this communication, and (ii) is not intended or written to be used, and cannot be used by any taxpayer, for the purpose of avoiding U.S. tax penalties. You are urged to consult with your tax advisor as to the tax consequences of the transaction to you in light of your particular circumstances, including the applicability and effect of any state, local or foreign tax laws.

You are advised to consult your own tax adviser with respect to the specific tax consequences to you of holding or disposing of pSivida's ADSs or ordinary shares.

### Taxation of Dividends Paid on ADSs or Ordinary Shares

Subject to the rules applicable to passive foreign investment companies, described below, a U.S. Holder will be required to include in gross income as ordinary income an amount equal to the U.S. dollar value of any distribution, plus any Australian tax withheld, paid on a pSivida ADS or ordinary share on the date the distribution is received by the depositary or the U.S. Holder, as the case may be, based on the exchange rate on that date, to the extent the distribution is paid out of pSivida's current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Generally, any gain or loss resulting from the conversion of Australian dollars into U.S. dollars will be ordinary income or loss. A distribution in excess of earnings and profits will be treated first as a nontaxable return of capital, reducing the U.S. Holder's basis in the pSivida ADS or ordinary share and, to the extent in excess of basis, will be treated as gain from the sale or exchange of the pSivida ADS or ordinary share. Notwithstanding the foregoing, we do not intend to maintain calculations of our earnings and profits as determined for U.S. federal income tax purposes. Accordingly, our distributions generally will be presumed to constitute dividends paid out of our earnings and profits. Our dividends will not qualify for the dividends received deduction generally available to corporations.

Noncorporate taxpayers are subject to U.S. tax on dividends paid by certain non-U.S. corporations to a maximum rate of 15% (or, with respect to dividends that otherwise would be taxed at the 10% or 15% rates, to 5%, except for taxable years beginning after December 31, 2007, for which the tax is eliminated). The reduced rates apply for purposes of both the regular tax and the alternative minimum tax. A dividend paid by a non-U.S. corporation qualifies for the reduced rate of tax if the stock on which the dividend is paid is readily tradable on an established securities market in the United States. ADRs listed on NASDAQ should qualify for such treatment. Even if the pSivida ADSs are so tradable at the time a dividend is paid, to qualify for the reduced rates, a shareholder must hold the share of stock on which the dividend is paid for more than 60 days during the 120-day period beginning 60 days before the ex-dividend date, disregarding for this purpose any period during which the taxpayer has an option to sell, is under a contractual obligation to sell or has made (and not closed) a short sale of substantially identical stock or securities, or, pursuant to Treasury regulations, has diminished its risk of loss by holding one or more other positions with respect to positions in substantially similar or related property. In addition, to qualify for the reduced rates, the taxpayer must not be obligated to make related payments with respect to positions in substantially similar or related property. Payments in lieu of dividends from short sales or other similar transactions will not qualify for the reduced rates. A taxpayer that receives an extraordinary dividend eligible for the new reduced tax rates must treat any loss on the sale of the stock as a long-term capital loss to the extent of the dividend. For purposes of determining the amount of a taxpayer's deductible investment interest expense, a dividend is treated as investment income only if the taxpayer elects to treat the dividend as not eligible for the new

A U.S. Holder will generally have the option of claiming the amount of any Australian withholding tax either as a deduction from gross income or as a dollar-for-dollar credit against the U.S. Holder's U.S. federal income tax liability. An individual who does not claim itemized deductions, but instead utilizes the standard deduction, may not claim a deduction for the amount of any Australian withholding tax, but that amount may be claimed as a credit against the individual's U.S. federal income tax liability. The amount of foreign income tax that may be claimed as a credit in any year is subject to limitations and restrictions, which must be determined on an individual basis by each shareholder. The limitations include, among others, rules that limit foreign tax credits allowable with respect to specific classes of foreign source income to the U.S. federal income tax otherwise payable with respect to each of those classes of income. The limitations on the foreign tax credit are exceedingly complex, and U.S. Holders therefore should consult their own tax advisers with respect to those limitations.

A U.S. Holder should not be eligible for a foreign tax credit against its U.S. federal income tax liability for Australian taxes we pay (other than Australian withholding taxes described above).

### Taxation of the Sale of ADSs or Ordinary Shares

Subject to the rules applicable to passive foreign investment companies, discussed below, upon the sale of a pSivida ADS or ordinary share, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference, if any, between the U.S. Holder's basis in the pSivida ADS or ordinary share and the amount realized on the sale. Capital gain or loss from the sale of a pSivida ADS or ordinary share held more than one year is long-term capital gain or loss. Noncorporate taxpayers pay a maximum federal income tax on adjusted net capital gain at 15 percent (or, with respect to adjusted net capital gain that otherwise would be taxed at the 10% or 15% rates, to 5%, except for taxable years beginning after December 31, 2007, for which the tax is eliminated). The rate applies to taxable years ending before January 1, 2009, after which the maximum tax rate on adjusted net capital gain for noncorporate taxpayers would revert back to 20 percent. The deductibility of a capital loss recognized on the sale of an ADS or ordinary share is subject to limitations.

In general, the rules regarding a deduction or credit for Australian withholding tax discussed above in "Taxation of Dividends Paid on ADSs or Ordinary Shares" also apply to any Australian tax paid on a sale of a pSivida ADS or ordinary share. See Item 10E, "Taxation — Commonwealth of Australia Taxation — Sale of Ordinary Shares" and ADSs". Except as discussed below, gain or loss recognized by a U.S. Holder on a sale of a pSivida ADS or ordinary share generally will be treated as U.S. source passive income or loss for purposes of the U.S. foreign tax credit limitations. In that case, unless a U.S. Holder has sufficient foreign source passive income from other transactions subject to foreign income tax at a rate sufficiently below the U.S. federal income tax rate applicable to that income, the U.S. foreign tax credit limitation rules could prevent the U.S. Holder from utilizing a foreign tax credit for part or all of any Australian tax paid on the gain. Nevertheless, U.S. Holders eligible for benefits under the current double taxation convention between Australia and the U.S., as amended, may be relieved of the source-related limitation on the use of such Australia foreign tax credits. Such persons are urged to consult with their tax advisors as to the potential benefits of this double tax convention. The foreign tax credit rules are complicated and could, in some cases, result in a U.S. holder being subject to taxation in Australia as well as in the United States on the same capital gain.

### Tax Consequences if pSivida Is a Passive Foreign Investment Company

In general, we will be a passive foreign investment company, or "PFIC", for any taxable year if either (1) 75 percent or more of pSivida's gross income in the taxable year is passive income, or (2) 50 percent or more of the average value of pSivida's assets in the taxable year produces, or is held for the production of, passive income. In general, for purposes of the asset test, a corporation can elect to take its assets into account at their adjusted basis, but only if the corporation is not publicly traded, and pSivida believes it is publicly traded for that purpose. The IRS takes the position that interest on working capital or any other cash is passive income and that the corresponding asset is an asset that produces or is held for the production of passive income. Unfavorable tax consequences for a U.S. Holder can occur if we are treated as a PFIC for any year while a U.S. Holder owns pSivida's ADSs or ordinary shares. These tax consequences can be mitigated if the U.S. Holder makes, or has made, a timely qualified electing fund election or election to mark to market the holder's ADSs or ordinary shares, and such election is in effect for the first taxable year during which the U.S. Holder owns pSivida's ADSs or ordinary shares that pSivida is a PFIC. If neither election is made, under the PFIC provisions, in any year in which the U.S. Holder either disposes of an ADS or an ordinary share at a gain or receives one or more "excess distributions," special rules apply to the taxation of the gain or the excess distributions. For purposes of these rules, "excess distributions" are the portion of our distributions in a taxable year, whether or not out of its earnings and profits, that exceed 125 percent of the average of our distributions, subject to adjustment to the extent there were excess distributions that the U.S. Holder received on the pSivida ADS or ordinary share during the previous three years or, if shorter, the U.S. Holder's holding period for the pSivida ADS or ordinary share on which the distributions are paid. A disposition of an ADS or ordinary share, for purposes of these rules, includes many transactions on which gain or loss is not realized under general U.S. federal income tax rules. The gain or the excess distributions must be allocated ratably to each day the U.S. Holder has held the pSivida ADS or ordinary share. Amounts allocated to each year are taxable as ordinary income in their entirety (not eligible for the reduced rate for dividends) and not as capital gain, and amounts allocable to prior years may not be offset by any deductions or losses. Amounts allocated to each such prior year are taxable at the highest rate in effect for that year and are subject to an interest charge at the rates applicable to deficiencies for income tax for those periods. In addition, a U.S. Holder's tax basis in an ADS or ordinary share that

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is acquired from a decedent would not receive a step-up to fair market value as of the date of the decedent's death but instead would be equal to the decedent's basis, if lower.

The special PFIC rules described above will not apply to a U.S. Holder if the U.S. Holder makes a timely election, which remains in effect, to treat pSivida as a qualified electing fund, or QEF, for the first taxable year in which the U.S. Holder owns a pSivida ADS or ordinary share and in which pSivida is a PFIC, provided it complies with certain reporting requirements. Instead, a U.S. Holder that has made a QEF election is required for each taxable year to include in income a pro rata share of pSivida's ordinary earnings as ordinary income and a pro rata share of its net capital gain as long-term capital gain, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. In order for the QEF election to be valid, we must provide U.S. Holders either (i) a statement showing such U.S. Holder's pro rata share of our ordinary earnings and net capital gain (calculated for U.S. tax purposes) for our taxable year, (ii) sufficient information to enable the U.S. Holder to calculate its pro rata share for such year, or (iii) a statement that we have permitted the U.S. Holder to inspect and copy its permanent books of account, records, and such other documents as may be maintained by pSivida that are necessary to establish that PFIC ordinary earnings and net capital gain are computed in accordance with U.S. income tax principles. In the event we are classified as PFIC, we intend to provide sufficient information to U.S. Holders to be able for them to enable them to calculate its pro rata share for such year. The QEF election is made on a shareholder-by-shareholder basis and can be revoked only with the consent of the IRS. A shareholder makes a QEF election by attaching to a timely filed U.S. federal income tax return a properly completed IRS Form 8621 that reflects the information provided in the PFIC Annual Information Statement supplied by pSivida to the shareholder and by filing a second copy of that form with the IRS Service Center in Philadelphia, Pennsylvania. Even if a QEF election is not made, if we are a PFIC in the hands of a U.S. Holder, that U.S. Holder must file each year a completed IRS Form 8621 with its U.S. federal income tax return. Although a QEF election generally cannot be revoked, if a U.S. Holder made a valid and timely QEF election for the first taxable year it owned an ADS or ordinary share and we are a PFIC, the QEF election does not apply in a later taxable year in which we do not satisfy the tests to be a PFIC. If a QEF election was not made for that first taxable year, certain elections can be made while a foreign corporation continues to satisfy the definition of a PFIC that, combined with a QEF election, can cause the QEF election to be treated as having been made for that first taxable year. Those elections may require the electing shareholder to recognize gain on a constructive sale or to be taxable on the shareholder's share of certain undistributed profits of the foreign corporation. If gain or income is recognized pursuant to one of those elections, the rules set forth in the preceding paragraph would apply to that gain or income. Even if a QEF election ceases to apply because in a later taxable year we cease to satisfy the tests to be a PFIC, the QEF election will apply again in any subsequent year in which we again satisfy the tests to be a PFIC. Moreover, if you sell all of the pSivida ADSs and ordinary shares you own and later reacquire other ADSs or ordinary shares of pSivida's, any QEF election you have made that remains in effect will apply to the pSivida ADSs and ordinary shares acquired later. Treasury regulations provide that the Commissioner of Internal Revenue has the discretion to invalidate or terminate a QEF election if the U.S. Holder or pSivida, or an intermediary, fails to satisfy the requirements for the QEF election.

The special PFIC rules described in the second preceding paragraph will not apply to a U.S. Holder if the U.S. Holder elects to mark the U.S. Holder's ADSs or ordinary shares to market each year, provided pSivida's ADSs or ordinary shares are considered "marketable stock" within the meaning of the Treasury regulations. A U.S. Holder that makes this election will recognize as ordinary income or loss each year an amount equal to the difference, if any, as of the close of the taxable year between the fair market value of the holder's pSivida ADSs or ordinary shares and the holder's adjusted tax basis in the pSivida ADSs or ordinary shares. Losses would be allowed only to the extent of net mark-to-market gain previously included in income by the U.S. Holder under the election for prior taxable years, reduced by losses allowed in prior taxable years. If the mark-to-market election were made, then the rules set forth in the second preceding paragraph would not apply for periods covered by the election. In general, the pSivida ADSs or ordinary shares will be marketable stock within the meaning of the Treasury regulations. A U.S. exchange is a "qualified exchange or other market" within the meaning of the Treasury regulations. A U.S. exchange is a "qualified exchange or other market" if such exchange is registered with the SEC or is established pursuant to the national market system established pursuant to section 11A of the Securities Exchange Act of 1934. A non-U.S. exchange is a "qualified exchange or other market" if the exchange is regulated or supervised by a governmental authority of the country where the market is located and (1) the exchange has trading volume, listing, financial disclosure, surveillance and other requirements designed to prevent fraudulent and manipulative acts and practices, to remove impediments to and perfect the mechanism of a free and open, fair and orderly market, and to protect

investors, and the laws of the country where the exchange is located and the rules of the exchange ensure that those requirements are actually enforced, and (2) the rules of the exchange effectively promote active trading of listed stocks. If a non-U.S. exchange has more than one tier or market level on which stock may be separately listed or traded, each such tier is treated as a separate exchange. NASDAQ and the ASX are each a qualified exchange within the meaning of the Treasury regulations. Thus, we believe that both the pSivida ADSs and the ordinary shares are "marketable stock" within the meaning of the Treasury regulations. If a U.S. Holder makes a mark-to-market election, but does not make that election for the first taxable year in which the U.S. Holder owns a pSivida ADS or ordinary share and in which we are a PFIC, and if the U.S. Holder had not made a QEF election for that first such taxable year, the rules set forth in the second preceding paragraph will apply to any distributions on a pSivida ADS or ordinary share in the year of the mark-to-market election, to any gain recognized on an actual sale of a pSivida ADS or ordinary share in that year and to any gain recognized in that year pursuant to the mark-to-market election. The mark-to-market rules generally continue to apply to a U.S. Holder who makes the mark-to-market election, even in years we do not satisfy the tests to be a PFIC.

A U.S. Holder who owns pSivida ADSs or ordinary shares during a year we are a PFIC generally will remain subject to the rules set forth in the third preceding paragraph for all taxable years if the U.S. Holder has not made a QEF election or a mark-to-market election, for the first taxable year in which the U.S. Holder owns a pSivida ADS or ordinary share and in which we are a PFIC. In that event, those rules will apply to any gains on dispositions of pSivida ADSs or ordinary shares and to any "excess distributions." It is, however, possible for a U.S. Holder to avoid this "once a PFIC, always a PFIC" result by electing to treat all of the U.S. Holder's pSivida ADSs and ordinary shares as sold for their fair market value as of the last day of the last taxable year we satisfy the tests to be a PFIC, provided the statute of limitations has not run for that year. If a gain is recognized on that constructive sale, the rules set forth in the third preceding paragraph would apply to that gain.

A dividend from a foreign corporation that otherwise would qualify for the 15 percent maximum tax rate does not qualify for that rate if the foreign corporation is a PFIC in either the taxable year of the dividend or the preceding taxable year.

We believe that the IRS would consider it to have been a PFIC in each of its past three fiscal years. However, we do not know whether it will be classified as a PFIC in the year ending June 30, 2006 or thereafter because the tests for determining PFIC status are applied annually, and it is difficult to make accurate predictions of future income and assets, which are relevant to this determination. In the event we are classified as a PFIC, it intends to provide U.S. Holders with sufficient information to enable them to make a QEF election if so desired. U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISERS ABOUT THE PFIC RULES, INCLUDING THE CONSEQUENCES TO THEM OF MAKING A QEF ELECTION OR A MARK-TO-MARKET ELECTION WITH RESPECT TO PSIVIDA'S ORDINARY SHARES IN THE EVENT THAT WE QUALIFY AS A PFIC.

#### Backup Withholding Tax and Information Reporting Requirements

U.S. backup withholding tax and information reporting requirements generally apply to payments to non-corporate holders of pSivida ADSs or ordinary shares. Information reporting will apply to payments of dividends on, and to proceeds form of the disposition of, pSivida ADSs or ordinary shares by a paying agent within the U.S. to a U.S. Holder, other than an "exempt recipient", including a corporation and certain other persons that, when required, demonstrate their exempt status. A paying agent within the U.S. will be required to backup withhold 28% of any payments of dividends on, and the proceeds from the disposition of, pSivida ADSs or ordinary shares within the U.S. to a U.S. Holder, other than an "exempt recipient," if the holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with applicable backup withholding requirements.

THE DISCUSSION ABOVE IS NOT INTENDED TO CONSTITUTE A COMPLETE ANALYSIS OF ALL TAX CONSIDERATIONS APPLICABLE TO AN INVESTMENT IN ADSS OR ORDINARY SHARES. YOU SHOULD CONSULT YOUR TAX ADVISER CONCERNING THE TAX CONSEQUENCES TO YOU IN YOUR PARTICULAR SITUATION.

#### F. DIVIDEND AND PAYING AGENTS

Not applicable.



# G. STATEMENT BY EXPERTS

Not applicable.

# H. DOCUMENTS ON DISPLAY

The documents concerning our company which are referred to in this annual report may be inspected at our offices at Level 12 BGC Centre, 28 The Esplanade, Perth WA 6000, Australia. We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, and, in accordance therewith, are required to file reports, including annual reports on Form 20-F, and other information with the U.S. Securities and Exchange Commission. These materials, including this annual report and the exhibits thereto, may be inspected and copied at the Commission's public reference room in Washington, D.C. Please call the Commission at 1-800-SEC-0330 for further information on the public reference rooms. As a foreign private issuer, we will be required to make filings with the Commission by electronic means. Any filings we make electronically will be available to the public over the Internet at the Commission's website at http://www.sec.gov.

## I. SUBSIDIARY INFORMATION

Not applicable.

## ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have exposure to changes in foreign currency exchange rates and interest rates. We do not utilize derivative financial instruments or other financial instruments subject to market risk.

#### **Foreign Currency Exchange Rates**

We conduct operations in two principal currencies, the Pound Sterling and the Australian dollar. These two currencies operate as the two functional currencies for our 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 us 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 our 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.

AS Appreciation	
10%	15%
(469)	(703)
(546)	(818)
(1,015)	(1,521)
	( )

### **Interest Rates**

Cash deposits are held in call and deposit accounts and are subject to variable interest rates. We do not consider our exposure to interest rates to be significant.

## ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not applicable.

### PART II

## ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

## ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

## **ITEM 15. CONTROLS AND PROCEDURES**

On June 30, 2005, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934. The evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based on that evaluation, we have concluded that, as of such date, our disclosure controls and procedures were ineffective in that we had insufficient accounting personnel who have sufficient knowledge and experience in U.S. GAAP and the Securities and Exchange Commission accounting requirements. The accounting personnel who prepare our financial statements will need to be trained on the application of U.S. GAAP accounting pronouncements and standardized reconciliation templates will need to be improved to assist in the reconciliation process between A-IFRS and U.S. GAAP.

There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of such controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their controls objectives. Acknowledging this, we have designed the disclosure controls and procedures to provide such reasonable assurance.

No changes in our internal controls over financial reporting occurred during the period covered by this annual report that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

### ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Mr. Michael Rogers, chair of our audit committee, qualifies as an "audit committee financial expert" and is independent within the meaning of this Item 16A. For more information on Mr. Rogers, see Item 6A, "Directors and Senior Management." For more information on the audit committee, see Item 6C, "Board Practices — Existing Board Committees - Audit and Compliance Committee".

## **ITEM 16B. CODE OF ETHICS**

We have adopted a code of ethics as defined in this Item 16B. The code of ethics applies to our chief executive officer, chief financial officer, chief accounting officer and persons performing similar functions. Our code of ethics is available in the corporate governance section of our website, <u>www.psivida.com</u>. For a brief description of the code of ethics, see Item 6C, "Board Practices — Conduct and Ethics".

## ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

### Audit and Non-Audit Fees

For purposes of this Form 20-F Annual Report and other SEC filings, the Company's independent registered public accounting firm is Deloitte Touche Tohmatsu. For statutory reporting purposes and filings with the ASX and ASIC in Australia, the Company's auditor was Ernst & Young for the fiscal years ended June 30, 2005 and 2004. Deloitte Touche Tohmatsu was also appointed for the Company's statutory auditor in November 2005 following the resignation of Ernst & Young from this position.

The following table sets forth the fees billed to us by our statutory auditor, Ernst & Young and its affiliates, during the fiscal years ended June 30, 2005 and 2004.

		As of June 30		
		2005		2004
-	(In	thousands of A	Australian	Dollars)
Fees				
Audit fees(a)	A\$	24,240	A\$	16,500
Audit-related fees				—
Tax fees		—		—
All other fees		1,020		6,000
Total	A\$	25,260	A\$	22,500

(a) Audit fees billed by Ernst & Young relate to the statutory audit of our annual financial statements for ASX and ASIC in Australia.

The following table sets forth the fees billed to us by our current independent registered public accounting firm, Deloitte Touche Tohmatsu and its affiliates, during the fiscal years ended June 30, 2005 and 2004.

	As of Jur	ie 30
	2005	2004
	(In thousands of Aus	tralian Dollars)
Fees		
Audit fees(b)	A\$ 681,191	A\$ 30,393
Audit-related fees	—	
Tax fees	9,496	
All other fees	4,936	
Total	A\$ 695,623	A\$ 30,393

(b) Audit fees billed by Deloitte Touche Tohmatsu relate to the audit of financial statements and review of SEC filings for the purposes of the Company's Registration Statement on Form 20-F lodged in January 2005, as well as the Annual Report on Form 20-F for the year ended June 30, 2005, as well as for the audit of subsidiary companies in the years ended June 30, 2005 and 2004.

## Audit Committee Pre-Approval Policies and Procedures

Our audit and compliance committee approves all audit and non-audit services provided by Deloitte Touche Tohmatsu, our current principal accountant, and other external auditors and may not engage external auditors to perform any non-audit/assurance services that may impair the external auditor's judgment or independence. In the fiscal years ending June 30, 2005 and June 30, 2004, all of the fees paid to Ernst & Young, our former principal accountant, were approved by the audit and compliance committee.

### ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

# ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

## ITEM 17. FINANCIAL STATEMENTS

Not applicable.

## **ITEM 18. FINANCIAL STATEMENTS**

See pages F-1 through F-61.

### **ITEM 19. EXHIBITS**

Documents filed as exhibits to this report.

Exhibit Exhibit No. Title

- 1.1 Constitution of pSivida Limited, dated April 7, 2004 (b)
- 2.1 Deposit Agreement, by and among pSivida Limited, Citibank, N.A. and the Holders and Beneficial Owners of American Depositary Shares Evidenced by American Depositary Receipts Issued Thereunder (c)
- 3.1 Deed Poll, dated October 26, 2004, executed by QinetiQ (b)
- 4.1 Rules of the pSivida Limited Employee Share Option Plan (b)
- 4.2 Collaboration Agreement among pSiOncology Pte. Ltd., Singapore General Hospital Pte. Ltd. and SGH Technology Ventures Pte. Ltd., dated July 24, 2002 (b) (g)
- 4.3 Process Development and Manufacturing Agreement between pSiMedica Limited and AEA Technology QSA GmbH, dated March 4, 2004 (b) (g)
- 4.4 Agreement among Beijing Med-Pharm Corp., pSiMedica Ltd. and pSiOncology Pte. Ltd., dated October 27, 2005, as amended on July 24, 2002 (g) (h)
   4.5 Merger Agreement, dated October 3, 2005, among pSivida Limited, pSivida Inc., and Control Delivery Systems Inc. (d)
- 4.6 Form of Registration Rights Agreement, between pSivida Limited and stockholders of Control Delivery Systems, Inc., dated as of December 30, 2005 (a)
- 4.0 Form of Registration Rights Agreement, between postula Linned and stockholders of Control Denvery Systems, inc., dated as of December 39, 2005 (a
- 4.7 Securities Purchase Agreement, dated October 5, 2005, between pSivida Limited and the investor listed on the Schedule of Buyers attached thereto (e)
- 4.8 Form of Subordinated Convertible Note in the principal amount of US\$15,000,000, dated as of November 16, 2005 (e)
  4.9 Form of Warrant to Purchase ADRs for the purchase of up to 633,803 ADRs, dated as of November 16, 2005 (e)
- 4.10 Form of Registration Rights Agreement, between Castelrigg Master Investments and pSivida Limited, dated as of November 16, 2005 (e)
- 4.11 Letter Agreement, dated November 15, 2005, relating to the Securities Purchase Agreement, dated October 5, 2005(e)
- 4.12 Amended and Restated License Agreement, between Control Delivery Systems, Inc. and Bausch & Lomb Incorporated dated December 9, 2003, as amended on June 28, 2005 (a) (i)
- 4.13 Collaboration Agreement, between Control Delivery Systems, Inc. and Alimera Sciences, Inc. dated February 11, 2005, as amended on February 23, 2005 and May 11, 2005 (a) (i)
- 4.14 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of October 20, 1991, including amendment (f) (i)
- 4.15 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of October 31, 1995 (f) (i)
- 4.16 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of September 9, 1997 (f) (i)
- 4.17 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of September 9, 1997 (f) (i)
- 4.18 License Agreement, the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of September 9, 1997 (f) (i)

Exhibit Exhibit

- 4.19 Commercial Sublease, between Exergen Corporation, and Control Delivery Systems, Inc., dated as of April 6, 2005 (a)
- 4.20 Amended and Restated Control Delivery Systems, Inc. Change of Control Agreement, between CDS and Paul Ashton, dated August 17, 2004 (a)
- 4.21 Amended and Restated Control Delivery Systems, Inc. Change of Control Agreement, between CDS and Michael Soja, dated August 17, 2004 (a)
- 4.22 Amended and Restated Control Delivery Systems, Inc. Change of Control Agreement, between CDS and Lori Freedman, dated August 17, 2004 (a)
- 4.23 Severance Agreement, between CDS and Paul Ashton, dated February 20, 2004 (a)
- 4.24 Severance Agreement, between CDS and Michael Soja, dated February 20, 2004 (a)
- 4.25 Severance Agreement, between CDS and Lori Freedman, dated February 20, 2004 (a)
- 4.26 First Amendment to Control Delivery Systems, Inc. Severance Agreement between CDS and Paul Ashton, dated August 17, 2004 (a)
- 4.27 First Amendment to Control Delivery Systems, Inc. Severance Agreement between CDS and Michael Soja, dated August 17, 2004 (a)
- 4.28 First Amendment to Severance Agreement between CDS and Lori Freedman, dated August 17, 2004 (a)
- 4.29 Control Delivery Systems, Inc. Restricted Stock Award Agreement, between CDS and Paul Ashton, dated August 16, 2004 (a)
- 4.30 Control Delivery Systems, Inc. Restricted Stock Award Agreement, between CDS and Michael Soja, dated August 16, 2004 (a)
- 4.31 Control Delivery Systems, Inc. Restricted Stock Award Agreement, between CDS and Lori Freedman, dated August 16, 2004 (a)
- 4.32 Retention Agreement, between CDS and Paul Ashton, dated September 29, 2005 (a)
- 4.33 Retention Agreement, between CDS and Michael Soja, dated September 29, 2005 (a)
- 4.34 Retention Agreement, between CDS and Lori Freedman, dated September 29, 2005 (a)
- 4.35 Non-Competition Agreement, between pSivida Limited and Paul Ashton, dated October 3, 2005 (a)
- 4.36 Stock Option Agreements, between CDS and Paul Ashton, dated July 10, 2002 (a)
- 8.1 List of subsidiaries (a)
- 12.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended (a)
- 12.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended (a)
- 13.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (a)
- 13.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (a)

- (b) Incorporated by reference to the registrant's filing on Form 20-F (Commission file number 000-51122) filed on January 20, 2005.
- (c) Incorporated by reference to the registrant's filing on Form F-6 (Commission file number 333-122158) filed on January 19, 2005.
- (d) Incorporated by reference to the registrant's later filing on Form F-6 (Commission file number 333-122158) filed on October 4, 2005.
- (e) Incorporated by reference to the registrant's earlier filing on Form F-6 (Commission file number 333-122158) filed on November 15, 2005. The final versions of documents denoted as "form of" have been omitted pursuant to Rule 12b-31. Such final versions are substantially identical in all material respects to the filed versions of such documents provided that the name of the investor, and the investor's and/or pSivida's signature are included in the final versions.
- (f) Incorporated by reference to Control Delivery Systems' filing on Form S-1 (Commission file number 333-51954) filed on December 15, 2000.
- (g) Incorporated by reference to Beijing Med-Pharm corporations's Filing on Post-Effective Amendment No. 3 to S-1 (Commission file number 333-121957) filed on November 15, 2005.
- (h) Confidential treatment has been granted for portions of this exhibit.
- (i) Confidential treatment has been requested for portions of this exhibit. An unredacted version of this exhibit has been filed separately with the Commission.

<sup>(</sup>a) Filed herewith.

### SIGNATURES

The registrants hereby certify that they meet all of the requirements for filing on Form 20-F and that they have duly caused and authorized the undersigned to sign this annual report on their behalf.

By: /s/ Gavin Rezos

Name: Gavin Rezos Title: Managing Director

By: <u>/s/ Aaron Finlay</u> Name: Aaron Finlay

Title: Chief Financial Officer and Company Secretary

Date: January 18, 2006

# PSIVIDA LIMITED AND SUBSIDIARIES INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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## 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 (January 12, 2006 as to Note 19)

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

		As at 30 Ju	1e
	Notes	2005 \$	2004 \$
Current Assets	Notes	<u> </u>	<u> </u>
Cash assets	17(a)	12,892,061	31,350,656
Receivables	6	709,418	340,482
Other	7	322,933	38,958
Total Current Assets		13,924,412	31,730,096
Non-Current Assets			
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
Total Non-Current Assets		68,110,901	8,636,962
Total Assets		82,035,313	40,367,058
Current Liabilities			
Payables	10	1,967,718	1,844,960
Payables, related party	10, 21(f)	50,102	37,144
Provisions	11	29,879	56,011
Total Current Liabilities		2,047,699	1,938,115
Total Liabilities		2,047,699	1,938,115
Net Assets		79,987,614	38,428,943
Equity			
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
Total Equity		79,987,614	38,428,943

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)

		,	Years Ended 30 June		Period from Inception of Development Stage (1 Dec 2000)
	Notes	2005 \$	2004 \$	2003 \$	to 30 June 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)
Loss from ordinary activities before income					
tax		(15,125,719)	(7,518,976)	(5,356,328)	(32,849,777)
Income tax expense relating to ordinary					
activities	5	_	_		—
Net loss before outside equity interest		(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
Net loss attributable to members of the parent entity		(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)

			Period from Inception of Development Stage		
			(1 Dec 2000) to 30 June		
	Notes	2005 \$	2004 \$	2003 \$	2005 \$
Cash flows from operating activities					
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)	(12,304,598)	(7,821,466)	(4,554,867)	(27,586,335)
Cash flows from investing activities					
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		(8,055,182)	(527,168)	(51,948)	(8,049,861)
Cash flows from financing activities		i			
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		3,639,078	36,953,447	852,567	49,669,348
Net (decrease)/ increase in cash held		(16,720,702)	28,604,813	(3,754,248)	14,033,152
Cash at the beginning of the financial period		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		(1,737,893)	1,565,709	(117,127)	(1,738,091)
Cash at the end of the financial period	17(a)	12,892,061	31,350,656	1,180,134	12,892,061

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 S	Deficit Accumulated Prior to Development Stage S	Deficit Accumulated During Development Stage S	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		,,	(-))-)	( ) <sup>2</sup> - ) <sup>2</sup> - )		
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	10,010,000	5,000,500				5,000,000
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
Balance, 50 Julie 2005	217,312,100	107,005,055	(3,013,101)	(24,105,001)	20,701	/9,90/,014

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<sup>TM</sup>. BioSilicon<sup>TM</sup> 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

### 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.



## 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.



## 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:

Leasehold improvements	Lesser of the lease term and the useful economic life
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<sup>TM</sup> intellectual property rights royalty free. pSiMedica also owns the patented rights to BioSilicon<sup>TM</sup>, 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.



## 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.

## 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

## 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
Total cost of acquisition	59,224,568

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:

Item	To	Total Fair Value		Acquired Interest 55.28%	
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)	
Intangible assets					
License	\$	64,400,000	\$	35,600,320	
Patents	\$	25,000,000	\$	13,820,000	
Total			\$	49,340,901	
Consideration			\$	59,224,568	
Initial goodwill arising under A-GAAP			\$	9,883,667	

### 3. Revenue from ordinary activities

		Years Ended 30 June		
	2005 \$	2004 \$	2003 \$	
Revenues from ordinary activities				
Interest income on bank deposits	667,310	325,479	110,675	
Other revenue	161,666	56,200	_	
Total revenue from ordinary activities	828,976	381,679	110,675	

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

# 4. Expenses and (Losses)/ Gains

# (a) Expenses

	Years Ended 30 June		
	2005 2004 S		2003 \$
Depreciation and amortisation of non-current assets			
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
	1,029,382	39,360	37,835
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
Total depreciation and amortisation of non-current assets	1,635,300	346,728	315,700
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)

## 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

2005	
2000	2004 \$
Current	
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.

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

#### 7. Other assets

	As at 30 June	
	2005 \$	2004 \$
Current		
Prepayments	322,933	38,958
Non-current		
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

<sup>(</sup>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.

 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.

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

## 8. Property, plant and equipment, net

	As at 30 June	
	2005	2004
	\$	\$
Plant and equipment		
At cost	2,439,455	1,360,533
Accumulated depreciation	(1,119,916)	(699,938)
	1,319,539	660,595
Leasehold improvements		
At cost	155,799	14,214
Accumulated depreciation	(30,188)	(5,110)
	125,611	9,104
Construction in progress(i)		
At cost	1,828,513	
Total property, plant and equipment		
At cost	4,423,767	1,374,747
Accumulated depreciation	(1,150,104)	(705,048)
	3,273,663	669,699

(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.

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

As at 30 Juna

64,837,238

7,934,622

## (a) Reconciliations

Reconciliations of the carrying amounts for each class of property, plant and equipment are set out below:

	As at 30 Jun	e
	2005	2004
Plant and equipment	<u></u>	3
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	1,319,539	660,595
Leasehold improvements		
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	125,611	9,104
Construction in progress		
Carrying amount at beginning of year	_	—
Additions	1,904,551	
Net foreign currency movements	(76,038)	—
Carrying amount at end of year	1,828,513	
9. Intangibles		
Intellectual property — at cost(i)	55,927,494	7,934,622
Goodwill on acquisition(ii)	9,883,667	
Accumulated amortization — goodwill	(973,923)	

(i) The intellectual property comprises the licence to develop applications for BioSilicon<sup>TM</sup> 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.

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

## 10. Payables

	As at 30 Ju	ne
	2005	2004
	<u> </u>	\$
Current		
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

Current			
Provision for employee entitlements	29,879		56,011
	-	Consolid	ated
		2005	2004
	<u> </u>	Number	Number
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.

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

# 12. Contributed equity

## (a) Contributed equity

	As at 30 J	une
	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
	F	-20		

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

Details of share issuances are as follows:

Date	Details	Number		e price S	Total S
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	50,021,572			34,355,798
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	,			,
č	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	65,374,381			57,925,853

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

## (c) Share options

	ercise rice	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
			19,965,000	14,681,537	(15,570,000)	(104,824)	18,971,713

\* 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	
	18,971,713	\$	0.97	

# 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.



## 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	16,921,713	7,095,000	2,700,000

### *(i)* Balance at beginning of financial year

Options — Series 2005	Number	Grant Date	Vesting Date	Expiry Date	kercise Price S
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
	7,095,000				

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

## (ii) Granted during financial year

Options — Series 2005	Number	Grant Date	Vesting Date	Expiry Date	tercise Price S
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
	12,631,537				

Options — Series 2004	Number	Grant Date	Vesting Date	Expiry Date	xercise Price \$
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
	4,395,000				

Options — Series 2003	Number	Grant Date	Vesting Date	Expiry Date	ercise rice \$
Issued 1 November 2002	520,000	1/11/02	1/11/03	31/12/04	\$ 0.20
	520,000				

(iii) Exercised during financial year

Options — Series 2005	Number	Grant Date	Vesting Date	Expiry Date	cercise Price \$
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
	(1,050,000)				

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

## (iv) Transferred during financial year

Options — Series 2005	Number	Grant Date	Vesting Date	Expiry Date	Exercise Price \$
Issued 31 December 2001	(1,650,000)	31/12/01	13/10/03	31/12/04	\$ 0.40
	(1,650,000)				

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

Options — Series 2005	Number	Grant Date	Vesting Date	Expiry Date	cercise Price \$
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>Options — Series 2003</u> Issued 1 November 2002	<u>Number</u> (20,000) (20,000) F-25	Grant Date 1/11/02	Vesting Date 1/11/03	Expiry Date 31/12/04	rercise Price \$ 0.20

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

## (vi) Balance at end of financial year

Options — Series 2005	Number	Grant Date	Vesting Date	Expiry Date	ercise Price \$
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
	16,921,713				

Options — Series 2004	Number	Grant Date	Vesting Date	Expiry Date	cercise 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
	7,095,000				

Options — Series 2003	Number	Grant Date	Vesting Date	Expiry Date	ercise rice \$
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
	2,700,000				

## 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.



## 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
	\$	<u> </u>
Foreign currency translation	(272,067)	78,220
Option premium	292,828	
	20,761	78,220

## (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	(272,067)	78,220

### (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		292,828	_
<ul><li>14. Accumulated deficit</li><li>(a) Deficit accumulated prior to development stage</li></ul>			
Balance at end of year		(3,813,181)	(3,813,181)
F	28		

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

## (b) Deficit accumulated during development stage

s         s           Balance at beginning of year         (9,377,278)         (5,694,072)           Net loss attributable to members of the Company         (14,726,523)         (3,683,202)	
Net loss attributable to members of the Company $(14.726.523)$ $(3.683.204)$	3)
	<u>(5)</u>
Balance at end of year (24,103,801) (9,377,278	8)

### 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		1,583,200

## 16. Investments in controlled entities

		Ownership	Interest
	Country of incorporation	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.

## 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
	12,892,061	31,350,656

## (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	(12,304,598)	(7,821,466)	(4,554,867)

## (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.

## 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.

## 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\$4.3 million (\$5.7 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.

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<sup>TM</sup>. 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.

On 30 December, 2005, the Company completed its acquisition of 100% of the outstanding equity of Control Delivery Systems Inc. ("CDS"). CDS has been renamed pSivida Inc.

This acquisition is an integral part of the Company's on-going US growth strategy. CDS' portfolio of products and product candidates includes two approved and marketed products, one Phase III product and other early-stage product candidates. The acquisition of CDS will bring additional product development and regulatory expertise to the Company's management team and provide the Company with an operating base in the Boston biotech hub, enhancing its overall visibility as well as access to the US scientific and investment communities.

The estimated purchase price of CDS of \$118,764,446, as determined in accordance with A-IFRS, consists of:

- \$114,170 cash;
- 161,047,790 ordinary fully paid shares of the Company, represented by 16,104,779 American Depositary Shares, or ADSs, with an estimated fair value of \$114,343,931 (\$0.71 per share, represented by US\$5.169 per ADR);
- 1,724,460 share options in the Company, represented by 172,446 warrants over ADSs with a Black Scholes estimated fair value of \$686,345; and
- direct acquisition costs of \$3,620,000.

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 this disclosure is preliminary and has been made solely for the purposes of developing such disclosure in the consolidated financial statements. The amounts ultimately recorded will be based on an independent valuation, expected to be finalized during the year ending June 30, 2006.

Following is a preliminary estimate of the allocation of the purchase price at December 30, 2005:

	Total fair value (in Australian dollars)
Cash	228,464
Receivables	78,482
Other	280,537
Patents	120,000,000
In-Process Research and Development	2,741,706
Property, Plant and Equipment	622,608
Payables	(4,820,060)
Deferred Revenue	(1,826,699)
Deferred Tax Liability, Net	(29,100,000)
Total	88,205,038
Purchase price	118,764,446
Goodwill	30,559,408

A preliminary estimate of \$120 million has been allocated to amortizable intangible assets consisting of patents with a weighted average useful life of twelve years. Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired and is not deductible for tax purposes. A preliminary estimate of \$30.6 million has been allocated to goodwill. The preliminary purchase price allocation for CDS is subject to revision as more detailed analysis is completed and additional information on the fair values of CDS's assets and liabilities becomes available. The amounts ultimately recorded will be based on an independent valuation, expected to be finalized during the year ending June 30, 2006. Any change in the fair value of the net assets of CDS will change the amount of the purchase price allocable to goodwill. The financial effects of this transaction are not reflected in the accounts as at 30 June 2005. On 30 December 2005, on the close of the CDS acquisition, Dr Paul Ashton was appointed as a director of the Company.

On 11 January 2006, the Company announced that it had appointed Ms. Heather Zampatti as a non-executive director of the Company. The Company also announced the resignation of Ms. Alison Ledger as a director.

### 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

(2,765,153)

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

	Number	Number	Number
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		<u> </u>	
Adjusted weighted average number of ordinary shares used in calculating basic and diluted loss per share	207,802,540	126,990,066	101,281,292

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

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.

18,971,713

23,700,000

19,965,000

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 Kluczewska Managing Director, AION Diagnostics Limited
- Mr Steve Connor Operations Director, pSiMedica Limited
- Dr Jill Ogden Commercialization Director, pSiMedica Limited



## 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) S	Total \$	Total Cash-based Remuneration S
2005							
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
Total	940,704	125,000	22,006	1,189	2,332,451	3,421,350	1,088,899
2004							
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
Total	910,020	290,000	70,281		889,350	2,159,651	1,270,301

\* These options had no taxable value at the date of issue.

## 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
	\$	S	\$	\$	\$	\$	\$
2005							
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 Kluczewska	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
Total	897,647	42,500	77,804	22,728	1,311,230	2,351,909	1,040,679
2004							
Dr A Kluczewska	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
Total	734,525	25,000	86,115	16,152	295,572	1,157,364	861,792

\* These options had no taxable value at the date of issue.

 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.

### 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 Kluczewska 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  $\pounds$ 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  $\pounds 125,000$  (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.

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

# Share options issued by pSivida Limited

				Terms and Conditions for Each Grant							
	Vested Number	Granted Number	Grant Date	Op	lue Per otion at nt Date** \$	Und Sh	llue of lerlying are at nt Date \$	Pri	ercise ce Per hare \$	Vesting Date	Expiry Date
Specified directors											
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
Total	4,650,000	4,650,000									
Specified executives											
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 Kluczewska	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
Total	2,500,000	2,800,000									

Share options issued by AION Diagnostics Limited

				Terms and Conditions for Each Grant					
	Vested Number	Granted Number	Grant Date	Op	lue Per otion at nt Date** \$	Unc Sh	alue of lerlying aare at ant Date \$	Exercise Price Per Share \$	Expiry Date
Specified directors									
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
Total		500,000							
Specified executives									
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 Kluczewska		395,040*	3 Feb 05	\$	0.40	\$	0.40	Nil	3 Feb 08
Total		559,640							

## 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 \$
Specified directors				
Mrs N Donovan	250,000	\$	0.20	—
	150,000	\$	0.40	
Total	400.000			

# (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
Specified directors				
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
Total	16,361,656		4,450,612	20,812,268
Specified executives				
Prof L Canham	—	_	3,909,579	3,909,579
Mr A Finlay		_	_	_
Dr A Kluczewska		_	_	
Mr S Connor		_	189,000	189,000
Dr J Ogden				_
Total			4,098,579	4,098,579

\* Opening balance at date of appointment

\*\* Closing balance at date of resignation

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

Share options issued by pSivida Limited

	Balance at 1 July 2004 Number	Granted As Remuneration Number	Net Other Change Number	Balance at 30 Jun 2005 Number
Specified directors				
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	11,800,000	4,650,000	(8,688,687)	7,761,313
Specified executives				
Prof L Canham		825,000	39,289	864,289
Mr A Finlay		900,000	_	900,000
Dr A Kluczewska	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	1,200,000	2,800,000	188,642	4,188,642

\* Opening balance at date of appointment

\*\* Closing balance at date of resignation

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

Share options issued by AION Diagnostics Limited

	Balance at 1 July 2004 Number	Granted As Remuneration Number	Net Other Change Number	Balance at 30 Jun 2005 Number
Specified directors				
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
Specified executives				
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.

## 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 Pty 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 Pty 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 \$
Amounts received or receivable for:			
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
	25,260	22,500	20,628
Amounts received or due and receivable by the auditors other than the statutory auditors of pSivida for:			
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	_	_
	695,623	30,393	38,600

## 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.

		United				
	Australia \$	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.

## 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 S	Fixed Interest Rate S	Non-Interest Bearing S	Total S	Weighted Average Interest Rate %
2005						
Financial assets						
Cash assets	17(a)	12,528,926	200,000	163,135	12,892,061	2.87
Receivables	6	_	_	709,418	709,418	n/a
		12,528,926	200,000	872,553	13,601,479	
Financial liabilities						
Payables	10	_	_	2,017,820	2,017,820	_
2004						
Financial assets						
Cash assets	17(a)	31,350,656	—	—	31,350,656	4.4
Receivables	6	_	_	340,482	340,482	n/a
		31,350,656		340,482	31,691,138	
Financial liabilities						
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

#### 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 halfyear 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

#### 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

## 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 is yet to determine whether 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.

## 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:

		Years Ended 30 June		
		2004 \$		2003 \$
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		(5,019,974)		(2,268,603)
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)
		30 June 2004 \$		1 July 2004 \$
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	=	37,794,705	=	7,140,316

## 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	2003	
		3	(As restated)	(As restated)	
Net loss in accordance with A-GAAP		(14,726,523)	(3,683,205)	(2,765,153)	
US GAAP adjustments:					
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)	<u> </u>	
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		(16,561,512)	(5,019,974)	(2,268,603)	
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	
		F-48			

## 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
US GAAP adjustments:			
Intangible assets			
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)
Goodwill			
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
Outside equity interest	(i)		
Consolidated statement of financial position classification		—	(1,583,200)
US GAAP adjustments			20,920
Total equity in accordance with US GAAP	-	87,650,337	37,794,705

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

Roll forward analysis of total equity under US GAAP

		Years Ended 30 June		
	_	2005	2004	
		\$	\$ (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		(16,561,512)	(5,019,974)	
Balance in accordance with US GAAP, end of year	_	87,650,337	37,794,705	

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.

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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 3	) June		
	2005		2004	2004		
	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
	2	005	2004		2003	_
Weighted average grant date fair value						
Exercise price exceeds market price	\$0.38		\$0.50		\$0.03	
Exercise price equals market price		\$0.40	<u> </u>			

#### 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



## 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:

#### <u>pSivida</u>

- 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



#### 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 End	ded 30 June			
	20	005	2	2004	2003		
	Number of Options	Weighted Average Exercise Price \$	Number of Options	Weighted Average Exercise Price \$	Number of Options		ghted Average cercise Price \$
Outstanding at beginning							
of year	6,595,000	0.52	2,700,000	0.36	2,200,0	00	0.40
Granted	12,041,537	1.08	3,895,000	0.61	520,0	00	0.20
Exercised	(1,050,000)	0.30	_	_			
Transferred	(1,650,000)	0.40					
Forfeited	(104,824)	0.98	_	_	(20,0	00)	0.20
Expired	_		_	_			
Outstanding at end of year	15,831,713	0.97	6,595,000	0.52	2,700,0	00	0.36
Exercisable at end of year	12,754,713	1.01	5,795,000	0.49			—
					2005	2004	2003
Weighted average grant date f	fair value						
Exercise price exceeds m	arket price				\$ 0.42	\$ 0.37	
Exercise price less than r	narket 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

## 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	<u>\$ 9.79</u>			
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.

## 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		—
		2005
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 \$	(A	2004 \$ s restated)	(A	2003 \$ s restated)
US GAAP net loss, as reported	(16,561,512)	, i	(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;

## 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.

## 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

## 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).

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).

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

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).

## (I) 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	(15,076,810)	(3,605,220)	(2,796,918)	

## (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)		
	(15,125,719)	(7,518,976)	(5,356,328)		

## 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" ("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

## 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 ("SFAS 154"), which replaces APB Opinion No. 20: "Accounting Changes" and SFAS No. 3: "Reporting Accounting Changes in Interim Financial Statements". The standard is 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.

## EXHIBIT INDEX

#### Exhibit Exhibit No. Title

- 1.1 Constitution of pSivida Limited, dated April 7, 2004 (b)
- 2.1 Deposit Agreement, by and among pSivida Limited, Citibank, N.A. and the Holders and Beneficial Owners of American Depositary Shares Evidenced by American Depositary Receipts Issued Thereunder (c)
- 3.1 Deed Poll, dated October 26, 2004, executed by QinetiQ (b)
- 4.1 Rules of the pSivida Limited Employee Share Option Plan (b)
- 4.2 Collaboration Agreement among pSiOncology Pte. Ltd., Singapore General Hospital Pte. Ltd. and SGH Technology Ventures Pte. Ltd., dated July 24, 2002 (b) (g)
- 4.3 Process Development and Manufacturing Agreement between pSiMedica Limited and AEA Technology QSA GmbH, dated March 4, 2004 (b) (g)
- 4.4 Agreement among Beijing Med-Pharm Corp., pSiMedica Ltd. and pSiOncology Pte. Ltd., dated October 27, 2005, as amended on July 24, 2002 (g) (h)
   4.5 Merger Agreement, dated October 3, 2005, among pSivida Limited, pSivida Inc., and Control Delivery Systems Inc. (d)
- 4.6 Form of Registration Rights Agreement, between pSivida Limited and stockholders of Control Delivery Systems, Inc., dated as of December 30, 2005 (a)
- 4.7 Securities Purchase Agreement, dated October 5, 2005, between pSivida Limited and the investor listed on the Schedule of Buyers attached thereto (e)
- 4.8 Form of Subordinated Convertible Note in the principal amount of US\$15,000,000, dated as of November 16, 2005 (e)
- 4.9 Form of Warrant to Purchase ADRs for the purchase of up to 633,803 ADRs, dated as of November 16, 2005 (e)
- 4.10 Form of Registration Rights Agreement, between Castelrigg Master Investments and pSivida Limited, dated as of November 16, 2005 (e)
- 4.11 Letter Agreement, dated November 15, 2005, relating to the Securities Purchase Agreement, dated October 5, 2005(e)
- 4.12 Amended and Restated License Agreement, between Control Delivery Systems, Inc. and Bausch & Lomb Incorporated dated December 9, 2003, as amended on June 28, 2005 (a) (i)
- 4.13 Collaboration Agreement, between Control Delivery Systems, Inc. and Alimera Sciences, Inc. dated February 11, 2005, as amended on February 23, 2005 and May 11, 2005 (a) (i)
- 4.14 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of October 20, 1991, including amendment (f) (i)
- 4.15 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of October 31, 1995 (f) (i)
- 4.16 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of September 9, 1997 (f) (i)
- 4.17 License Agreement, between the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of September 9, 1997 (f) (i)
- 4.18 License Agreement, the University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated as of September 9, 1997 (f) (i)
- 4.19 Commercial Sublease, between Exergen Corporation, and Control Delivery Systems, Inc., dated as of April 6, 2005 (a)
- 4.20 Amended and Restated Control Delivery Systems, Inc. Change of Control Agreement, between CDS and Paul Ashton, dated August 17, 2004 (a)
- 4.21 Amended and Restated Control Delivery Systems, Inc. Change of Control Agreement, between CDS and Michael Soja, dated August 17, 2004 (a)
- 4.22 Amended and Restated Control Delivery Systems, Inc. Change of Control Agreement, between CDS and Lori Freedman, dated August 17, 2004 (a)
- 4.23 Severance Agreement, between CDS and Paul Ashton, dated February 20, 2004 (a)
- 4.24 Severance Agreement, between CDS and Michael Soja, dated February 20, 2004 (a)
- 4.25 Severance Agreement, between CDS and Lori Freedman, dated February 20, 2004 (a)
- 4.26 First Amendment to Control Delivery Systems, Inc. Severance Agreement between CDS and Paul Ashton, dated August 17, 2004 (a)
- 4.27 First Amendment to Control Delivery Systems, Inc. Severance Agreement between CDS and Michael Soja, dated August 17, 2004 (a)

- Title
   First Amendment to Severance Agreement between CDS and Lori Freedman, dated August 17, 2004 (a)
- 4.29 Control Delivery Systems, Inc. Restricted Stock Award Agreement, between CDS and Paul Ashton, dated August 16, 2004 (a)
- 4.30 Control Delivery Systems, Inc. Restricted Stock Award Agreement, between CDS and Michael Soja, dated August 16, 2004 (a)
- 4.31 Control Delivery Systems, Inc. Restricted Stock Award Agreement, between CDS and Lori Freedman, dated August 16, 2004 (a)
- 4.32 Retention Agreement, between CDS and Paul Ashton, dated September 29, 2005 (a)
- 4.33 Retention Agreement, between CDS and Michael Soja, dated September 29, 2005 (a)
- 4.34 Retention Agreement, between CDS and Lori Freedman, dated September 29, 2005 (a)
- 4.35 Non-Competition Agreement, between pSivida Limited and Paul Ashton, dated October 3, 2005 (a)
- 4.36 Stock Option Agreements, between CDS and Paul Ashton, dated July 10, 2002 (a)
- 8.1 List of subsidiaries (a)
- 12.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended (a)
- 12.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended (a)
- 13.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (a)
- 13.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (a)

- (b) Incorporated by reference to the registrant's filing on Form 20-F (Commission file number 000-51122) filed on January 20, 2005.
- (c) Incorporated by reference to the registrant's filing on Form F-6 (Commission file number 333-122158) filed on January 19, 2005.
- (d) Incorporated by reference to the registrant's later filing on Form F-6 (Commission file number 333-122158) filed on October 4, 2005.
- (e) Incorporated by reference to the registrant's earlier filing on Form F-6 (Commission file number 333-122158) filed on November 15, 2005. The final versions of documents denoted as "form of" have been omitted pursuant to Rule 12b-31. Such final versions are substantially identical in all material respects to the filed versions of such documents provided that the name of the investor, and the investor's and/or pSivida's signature are included in the final versions.
- (f) Incorporated by reference to Control Delivery Systems' filing on Form S-1 (Commission file number 333-51954) filed on December 15, 2000.
- (g) Incorporated by reference to Beijing Med-Pharm corporations's Filing on Post-Effective Amendment No. 3 to S-1 (Commission file number 333-121957) filed on November 15, 2005.
- (h) Confidential treatment has been granted for portions of this exhibit.
- (i) Confidential treatment has been requested for portions of this exhibit. An unredacted version of this exhibit has been filed separately with the Commission.

Exhibit Exhibit No. Title

<sup>(</sup>a) Filed herewith.

#### FORM OF REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement, dated as of December 30, 2005, (this "Agreement"), is entered into by and among pSivida Limited, an Australian corporation ("Issuer"), and the securityholders of Control Delivery Systems, Inc., a Delaware corporation (the "Company"), named on the signature pages hereto (each a "Holder" and collectively, the "Holders").

#### RECITALS

A. WHEREAS, Issuer is a party to that certain Agreement and Plan of Merger, dated as of October 3, 2005 (the "Merger Agreement") that provides, among other things, that (i) pSivida Inc., a Delaware corporation and a wholly-owned subsidiary of Issuer ("Merger Subsidiary"), will be merged with and into the Company (the "Merger") with the Company continuing as the surviving corporation (the "Surviving Corporation"), and (ii) immediately after the Merger, Issuer will own all of the issued and outstanding equity interests of the Surviving Corporation.

B. WHEREAS, subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger (the "Closing"), the Holders shall receive or become entitled to receive American Depositary Shares of Issuer ("ADSs").

C. WHEREAS, as a condition precedent to the consummation of the transactions contemplated by the Merger Agreement, Issuer has agreed to grant the Holders certain registration rights, as set forth herein, with respect to the Registrable Securities (as defined herein).

#### AGREEMENT

NOW, THEREFORE, in consideration of the premises, and the mutual representations, warranties, covenants, and agreements hereinafter set forth, the parties hereto agree as follows:

#### 1. Definitions.

(a) Each capitalized term used but not defined herein shall have the meaning ascribed to such term in the Merger Agreement.

(b) "Commission" shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.

(c) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

(d) "Registrable Securities" means all of the ADSs issued to a Holder pursuant to the Merger Agreement, such number and type of securities to be equitably adjusted in the event of a stock split, stock dividend, combination, reclassification, merger or reincorporation. (e) "Registration Expenses" means all expenses incident to Issuer's performance of, or compliance with, this Agreement, including, without limitation, all registration, filing, listing and NASD fees, all fees and expenses of complying with securities or blue sky laws, all word processing, duplicating and printing expenses, messenger and delivery expenses, the fees and expenses of counsel for Issuer and of its independent public accountants, including the expenses of any special audits or "cold comfort" letters required by or incident to such performance and compliance, but excluding underwriting discounts and commissions, and transfer taxes, if any.

(f) "Rule 144" shall mean Rule 144 as promulgated by the Commission under the Securities Act, as such Rule may be amended from time to time, or any similar successor rule that may be promulgated by the Commission.

(g) "Rule 415" shall mean Rule 415 as promulgated by the Commission under the Securities Act, as such Rule may be amended from time to time, or any similar successor rule that may be promulgated by the Commission.

(h) "Transfer" shall mean any sale, assignment, conveyance, exchange, pledge, hypothecation, gift, disposal of or other parting with any indicia or aspect of title, ownership or possession, including without limitation, the withdrawal from the depositary of the underlying ordinary shares of pSivida Limited represented by one or more ADSs.

2. Shelf Registration Statement for Holders. Issuer shall use its commercially reasonable efforts to prepare and file with the Commission a "shelf" registration statement under the Securities Act for an offering to be made on a continuous basis pursuant to Rule 415 covering, along with any other securities that Issuer shall choose to include, all of the Registrable Securities held by a Holder or permitted transferee or assignee pursuant to Section 8 (the "Shelf Registration Statement"). Issuer shall use its commercially reasonable efforts to cause the Shelf Registration Statement (a) to become effective on or prior to one hundred eighty (180) days following the closing of the Merger (the "Required Registration Date") and (b) to remain effective for a period ending on the earliest to occur of (i) two (2) years from the date of effectiveness (subject to extension for any "black-out" period permitted by Section 6(a) or suspensions permitted by Section 3(f) hereof), or (ii) the first date (x) on which each Holder of Registrable Securities would be eligible to sell publicly, pursuant to Rule 144 within the volume limitations contained in subsection (e) (1) (i) of Rule 144, 110% of the Registrable Securities then held by such Holder, or (y) on which all Registrable Shares have been sold (the "Registration Rights Period"). The Shelf Registration Statement when declared effective (including the documents incorporated therein by reference) will comply as to form with all applicable requirements of the Securities Act and the Exchange Act. Notwithstanding the foregoing, Issuer shall have no obligation to include any of the Registrable Securities of any Holder in any Shelf Registration Statement pursuant to this Agreement when such Holder would be eligible to sell publicly, pursuant to Rule 144 within the volume limitations contained in subsection (e)(1)(i) of Rule 144, 110% of the Registrable Securities then held by such Holder.

3. Registration Procedures - Issuer. In connection with its obligations contained in Section 2 hereof, Issuer will, subject to the terms and conditions of this Agreement:

(a) subject to any "black-out" period permitted by Section 6(a), prepare and file with the Commission such amendments and supplements to the Shelf Registration Statement and any prospectus used in connection therewith as may be necessary to keep such registration statement effective and to comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such registration statement until the end of the Registration Rights Period;

(b) furnish to each Holder of Registrable Securities covered by the Shelf Registration Statement such number of conformed copies of such registration statement and of each such amendment and supplement thereto (in each case including all exhibits), such number of copies of the prospectus contained in such registration statement (including each preliminary prospectus and any summary prospectus) and any other prospectus filed under Rule 424 under the Securities Act, in conformity with the requirements of the Securities Act, and such other documents, in each case, as such Holder may reasonably request;

(c) use its commercially reasonable efforts to register or qualify, prior to the effective date of such registration, all Registrable Securities covered by the Shelf Registration Statement under such securities or blue sky laws of such jurisdictions as each Holder thereof shall reasonably request, to keep such registration or qualification in effect for so long as such registration statement remains in effect, and take any other action which may be reasonably necessary or advisable to enable such Holder to consummate the disposition in such jurisdictions of the securities owned by such Holder, except that Issuer shall not for any such purpose be required to: (i) qualify generally to do business as a foreign corporation in any jurisdiction wherein it would not but for the requirements of this Section 3(c) be obligated to be so qualified, (ii) subject itself to taxation in any such jurisdiction, or (iii) consent to general service of process in any such jurisdiction;

(d) use its commercially reasonable efforts to obtain all legal opinions and auditors' consents as may be required by applicable law.

(e) use its commercially reasonable efforts to cause, prior to the effective date of the Shelf Registration Statement, all Registrable Securities covered by such registration statement to be registered with or approved by such other governmental agencies or authorities as may be necessary to enable the Holder or Holders thereof to consummate the disposition of such Registrable Securities;

(f) (i) immediately notify each Holder of Registrable Securities covered by the Shelf Registration Statement, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the happening of any event or the existence of any condition as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances under which they were made, or, if in the opinion of counsel for Issuer, it is necessary to supplement or amend such prospectus to comply with law and, after such notice, (ii) except for periods described in Section 6 hereof or the time period for filing with the Commission information referred to in Section 3(a) hereof has not expired, promptly prepare and furnish to each Holder a supplement or amendment to such prospectus or otherwise update such prospectus so that such prospectus will not contain an untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading. The Issuer will extend the Registration Rights Period by the number of days during the period from and including the date of giving such notice to and including the date when the Holders shall have received copies of the revised prospectus;

(g) use its best efforts to list or admit all Registrable Securities covered by such registration statement on any securities exchange on which any of the Registrable Securities are then listed or any other trading market on which any of the Registrable Securities are then admitted for trading; and provide and cause to be maintained a depositary for all Registrable Securities; and

(h) pay all Registration Expenses relating to any such registration.

4. Failure to Register. In addition to any other remedies available to Holders under this Agreement or at law or equity, if no Shelf Registration Statement has been declared effective by the Required Registration Date or such Shelf Registration Statement is not available with respect to all Registrable Securities at any time on or after the Required Registration Date and during the Registration Rights Period (except during any "black-out" period permitted by Section 6(a) or any suspension permitted by Section 3(f) hereof) the Issuer shall cause to be wire transferred to an account specified by each Holder on the last business day of each month an amount, in immediately available United States funds, equal to:

1/30% x ND x MV

Where:

- ND = the number of days in such month that the Shelf Registration Statement has not been declared effective by the Required Registration Date or the Shelf Registration Statement is not available with respect to Registrable Securities that Issuer is then required to register pursuant to Section 2 or that may not otherwise be sold by such Holder immediately pursuant to Rule 144 without compliance with the registration requirements of the Securities Act ("Non-Rule 144 Stock"); and
- MV = the average of the closing price of Parent ADSs on The Nasdaq National Market for each of the ten (10) trading days ending on the trading day that is four (4) full trading days prior to the Closing Date of the Merger multiplied by the average number of shares of Non-Rule 144 Stock held by Holders on each of the days included in "ND" above.

# 5. Registration Procedures - Holders. Each Holder of Registrable Securities agrees as follows:

(a) that upon receipt of any notice from Issuer of the happening of any event of the kind described in Section 3(f), such Holder will forthwith discontinue such Holder's disposition of Registrable Securities pursuant to the registration statement relating to such Registrable Securities until such Holder's receipt of the copies of the supplemented or amended prospectus contemplated by Section 3(f) and, if so directed by Issuer, will deliver to Issuer all copies, other than permanent file copies, then in such Holder's possession of the prospectus relating to such Registrable Securities current at the time of receipt of such notice, and

(b) that it will immediately notify Issuer, at any time when a prospectus relating to the registration of such Registrable Securities is required to be delivered under the Securities Act, of the happening of any event as a result of which information previously furnished by such Holder to Issuer in writing for inclusion in such prospectus contains an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances under which they were made.

6. Black-Out Periods for Holders; Standstill.

(a) No Holder shall offer to sell or sell any Registrable Securities pursuant to the Shelf Registration Statement, and Issuer shall not be required to supplement or amend any Registration Statement or otherwise facilitate the sale of Registrable Securities pursuant thereto, during the 30-day period (or such lesser number of days until Issuer makes a relevant public disclosure or otherwise gives Holders notice of the termination of such period) immediately following the receipt by each Holder of a certificate of an authorized officer of Issuer to the effect that Issuer has determined in good faith that such offer, sale, supplement or amendment is likely to (i) interfere with or have a detrimental effect on the negotiation or completion of any material transaction that is being contemplated by Issuer (whether or not a final decision has been made to undertake such transaction) at the time the right to delay is exercised, or (ii) involve initial or continuing disclosure obligations that are likely to have a detrimental effect on the Issuer or its stockholders. Any period described in this Section 6(a) during which Holders are not able to sell shares of Registrable Securities pursuant to the Shelf Registration Statement is herein referred to as a "black-out" period. Issuer shall notify each Holder of the expiration or earlier termination of any "black-out" period (the nature and pendency of which need not be disclosed during such "black-out" period). The Issuer may exercise the rights provided by this Section 6(a) with respect to no more than an aggregate of sixty (60) days within any 365-day period; provided, (x) that no "black-out" period shall exceed thirty (30) consecutive days and (y) that the Issuer may not exercise the rights provided by this Section 6(a) for more than an aggregate of thirty (30) days within the first six months following the effectiveness of the Shelf Registration Statement.

(b) No Holder shall offer to sell or Transfer any Registrable Securities, pursuant to the Shelf Registration Statement or otherwise, during the six (6) month period immediately following the Closing. Notwithstanding the foregoing, a Holder may transfer Registrable Securities during such period (i) as a bona fide gift or gifts, provided that the donee or donees thereof agree to be bound in writing by the restrictions set forth herein, (ii) to any trust for the direct or indirect benefit of the Holder or the immediate family of Holder, provided that the trustee of the trust agrees to be bound in writing by the restrictions set forth herein, and provided further that any such transfer shall not involve a disposition for value, or (iii) to an Affiliate, partner, member or stockholder of the Holder or, with respect to any Holder that is an institutional investor, to another institutional investor under common management with such Holder, provided that the transferee agrees to be bound in writing by the restrictions set forth herein, or (iv) with the prior written consent of Issuer.

(c) No Holder shall offer to sell or Transfer any of any of the ordinary shares underlying the Registrable Securities (other than to an Affiliate, partner, member or stockholder of the Holder or to an institutional investor under common management with such Holder in compliance with the terms of Section 8 herein), including through trading on the Australian Stock Exchange, at any time prior to the earlier of: (a) the Issuer's subsequent lodgement with the Australian Securities and Investments Commission of a prospectus under the Corporations Act for fully paid ordinary shares of the Issuer (such prospectus incorporating the Shelf Registration Statement or extracts of the Shelf Registration Statement as deemed appropriate by the Issuer); or (b) the date which is 12 months after the closing of the Merger. The Issuer shall, on or prior to the Required Registration Date lodge such prospectus.

(d) Each Holder hereby agrees that, at the request of and for the benefit of the underwriter or underwriters of any underwritten public offering of ADSs or other securities of the Issuer for the account of the Issuer, for a period beginning seven days immediately preceding and ending not more than ninety (90) days following the effective date of the registration statement used in such offering, such Holder will not offer, sell, contract to sell, pledge, or otherwise dispose of, directly or indirectly, any ADSs or securities convertible into or exchangeable or exercisable for any ADSs (other than any transfers of a Holder to any Affiliate, partner, member or stockholder of such Holder (each of whom shall have furnished to the Issuer and the underwriters its written consent to be bound by the terms of this Agreement pursuant to Section 8)), enter into a transaction which would have the same effect, or enter into any swap, hedge or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of the ADSs, whether any such aforementioned transaction is to be settled by delivery of the ADSs or such other securities, in cash or otherwise, or publicly disclose the intention to make any such offer, sale, pledge or disposition, or to enter into any such transaction, swap, hedge or other arrangement, without, in each case, the prior written consent of such underwriter or underwriters; provided, however, that such Holder is at the time of such public offering an officer or director of the Issuer or is the holder of more than 5% of the outstanding capital stock of Issuer and that all officers and directors and all holders of more than 5% of the outstanding capital stock of the Issuer enter into lock-up agreements with such underwriter or underwriters for the same period and on the same terms.

#### 7. Indemnification.

(a) Indemnification by Issuer. Issuer will, and hereby does, to the full extent permitted by law indemnify and hold harmless each participating Holder of any Registrable Securities covered by any registration statement filed pursuant to Section 2 hereof, from and against any losses, claims, damages or liabilities, joint or several (or actions or proceedings, whether commenced or threatened, in respect thereof, whether or not such Holder is a party thereto, and including reasonable costs of investigation and legal expenses) (collectively, "Claims"), to which such Holder may become subject under the Securities Act or otherwise, insofar as such Claims arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in any registration statement under which such securities were registered under the Securities Act, any preliminary prospectus, final prospectus or summary prospectus contained therein, or any amendment or supplement thereto (if used during the period Issuer is required to keep the registration statement current) or any documents incorporated therein (collectively, "Registration Documents"), or any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading (in the case of a prospectus or preliminary prospectus, in light of the circumstances in which they were made), and Issuer will reimburse such Holder for any legal or any other expenses reasonably incurred by them in connection with investigating or defending any such Claim; provided, however, that Issuer shall not be liable in any such case to the extent that any such Claim or expense arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in any such Registration Document in reliance upon and in conformity with written information furnished to Issuer by such Holder for use in the preparation thereof. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of such Holder and shall survive the Transfer of such securities by such Holder.

(b) Indemnification by the Holders. Each Holder will, if Registrable Securities held by such Holder are included in any registration statement filed pursuant to Section 2 hereof, indemnify the Issuer, each of its directors, officers, legal counsel, and accountants, each Holder and each of their officers, directors and partners, and each person controlling such Holder (to the extent such Holder's Registrable Securities were included in such registration), against all claims, losses, damages and liabilities (or actions in respect thereof) arising out of or based on any untrue statement (or alleged untrue statement) of a material fact contained in any such registration statement, prospectus, offering circular or other document, or any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and will reimburse the Issuer, its directors, officers, partners, legal counsel, and accountants, the Holders, or control persons, for any legal or any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action, in each case to the extent, but only to the extent, that such untrue statement (or alleged untrue statement) or omission (or alleged omission) is made in such registration statement, prospectus, offering circular or other document in reliance upon and in conformity with written information furnished to the Issuer by such Holder and stated to be specifically for use therein; provided, however, that the obligations of such Holder hereunder will be limited to an amount equal to the net proceeds to such Holder (after deducting any underwriter's discounts and commissions and all other expenses paid by such Holder in connection with the registration in question) and shall not apply to amounts paid in settlement of any such claims, losses, damages or liabilities (or actions in respect thereof) if such settlement is effected without the consent of such Holder (which consent shall not be unreasonably withheld).

(c) Notices of Claims, etc. Promptly after receipt by an indemnified party of notice of the commencement of any action or proceeding involving a Claim referred to in the preceding subdivisions of this Section 7, such indemnified party will, if a claim in respect thereof

is to be made against an indemnifying party, give written notice to the latter of the commencement of such action; provided, however, that the failure of any indemnified party to give notice as provided herein shall not relieve the indemnifying party of its obligations under the preceding subdivisions of this Section 7, except to the extent that the indemnifying party is actually prejudiced by such failure to give notice. In case any such action is brought against an indemnified party, the indemnifying party shall be entitled to participate in and to assume the defense thereof, jointly with any other indemnifying party similarly notified to the extent that it may wish, and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party for any legal or other expenses subsequently incurred by the latter in connection with the defense thereof other than reasonable costs of investigation. No indemnifying party shall consent to entry of any judgment or enter into any settlement of any pending or threatened proceeding in respect of which an indemnified party is or could have been a party and indemnity could have been sought under Section 7(a) without the consent of the indemnified party which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such claim or litigation.

8. Transfer or Assignment of Registration Rights. The rights and obligations provided by this Agreement may be transferred or assigned by any Holder in connection with the transfer of such Holder's Registrable Securities to an Affiliate, partner, member or stockholder of such Holder or, with respect to any Holder that is an institutional investor, to another institutional investor under common management with such Holder, and any such transferee shall be deemed a Holder hereunder; provided that no Holder may assign its rights hereunder unless (i) its proposed assignee assumes all of the obligations of such Holder hereunder and (ii) Issuer is given written notice prior to any said transfer or assignment, containing the name and address of any such transferee.

9. Sales Pursuant to Rule 144. Each of the parties hereto acknowledges that the registration benefits provided in this Agreement will not affect the ability of the Holders to sell Registrable Securities pursuant to Rule 144 rather than pursuant to the Shelf Registration Statement.

10. Reports under the Exchange Act. With a view to making available to the Holders the benefits of Rule 144 promulgated under the Securities Act and any other rule or regulation of the Commission that may at any time permit such Holder to sell securities of the Issuer to the public without registration and with a view to making it possible for Holders to register the Registrable Securities pursuant to a registration statement on Form S-3 or Form F-3, as applicable, the Issuer agrees to use its commercially reasonable efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act;

(b) file with the Commission in a timely manner all reports and other documents required of the Issuer under the Securities  $\mbox{Act}$  and the Exchange  $\mbox{Act};$  and

(c) furnish to any Holder promptly upon request, to the extent necessary in order to enable such Holder to avail itself of any rule or regulation of the Commission that permits the

selling of any such securities without registration, a written statement by the Issuer as to its compliance with the reporting requirements of Rule 144 (at any time after the termination of the trading restrictions contained in Section 6(b)), the Securities Act and the Exchange Act (at any time after it has become subject to such reporting requirements), or as to its qualification as a registrant whose securities may be resold pursuant to Form S-3 (at any time after it so qualifies).

11. Termination of Registration Obligation. Any and all other provisions of this Agreement notwithstanding, in the event that the Issuer becomes a domestic U.S. issuer and as part of such transaction issues to all Holders securities in consideration of the Registrable Securities (the "Equivalent Securities") in a transaction that is registered under the Securities Act such that the Equivalent Securities are freely tradable under the Securities Act, then this Agreement will terminate upon the issuance of such registered Equivalent Securities and the rights and obligations of all parties hereunder shall cease, provided that any payment obligations then owing under Sections 3(h), 4 or 7 of this Agreement shall not be affected by such termination and such provisions shall remain in full force and effect with respect to such accrued obligations.

12. Notices. All notices, requests, demands, claims and other communications hereunder shall be in writing. Any notice, request, demand, claim, or other communication hereunder shall be deemed duly given (a) if personally delivered, when so delivered, (b) if mailed, three (3) business days after having been sent by registered or certified mail, return receipt requested, postage prepaid and addressed to the intended recipient as set forth below, (c) if given by telex or telecopier, once such notice or other communication is transmitted to the telex or telecopier number specified below and the appropriate answer back or telephonic confirmation is received, provided that such notice or other communication is promptly thereafter mailed in accordance with the provisions of clause (b) above, or (d) if sent through an overnight delivery, the day following being so sent:

(i) If to Issuer:

pSivida Limited Level 12, BGC Centre 28 The Esplanade, Perth WA 6000 Australia GPO Box 2535 Perth, WA 6831 Attention: Gavin Rezos Facsimile No.: +61 8 9226 5499

with a copy (which shall not constitute notice) to Parent's Counsel: Curtis, Mallet-Prevost, Colt & Mosle LLP 101 Park Avenue New York, NY 10178 Attention: Lawrence Goodman, Esq. Facsimile No.: (212) 697-1559

#### (ii) If to Holders:

To the address set forth on the signature pages hereto.

In the event that any of the Holders identified in this Agreement transfers Registrable Securities to a new Holder in accordance with Section 8 above, Issuer may provide notice to such Holder through notifying the original Holder identified herein. Any party may give any notice, request, demand, claim or other communication hereunder using any other means (including ordinary mail or electronic mail), but no such notice, request, demand, claim or other communication shall be deemed to have been duly given unless and until it actually is received by the individual for whom it is intended. Any party may change the address to which notices, requests, demands, claims and other communications hereunder are to be delivered by giving the other parties notice in the manner herein set forth.

13. Amendments. No change or modification of this Agreement or waiver of any provision hereof shall be valid, binding or enforceable as against (a) Issuer, unless the same shall be in writing and signed by Issuer, and (b) any Holder, unless the same shall be in writing and signed by Holders who own, in the aggregate, at least fifty per cent (50%) of the total number of Registrable Securities that Issuer is then required to register pursuant to Section 2 hereof at the time of such amendment; provided, however, that any such amendment or waiver that affects one Holder in a way that is materially adverse to such Holder relative to all other Holders cannot be effected without the written consent of such Holder and no additional or expanded obligations may be imposed on any Holder without the consent of such Holder.

14. No Waivers. No waiver by a party of any default, misrepresentation or breach of warranty or covenant hereunder, whether intentional or not, shall be deemed to extend to any prior or subsequent default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent occurrence. No failure or delay by a party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

15. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns, provided that no registration rights will be transferred other than in accordance with Section 8 hereof.

16. Governing Law. This Agreement shall be construed in accordance with and governed by the internal laws of the State of New York.

17. Counterparts. This Agreement may be signed in any number of counterparts and the signatures delivered by telecopy, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

18. Entire Agreement. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements, understandings and negotiations, both written and oral, between the parties with respect to the subject matter of this Agreement. Neither this Agreement nor any provision hereof is intended to confer upon any person other than the parties hereto any rights or remedies hereunder.

19. Captions. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. All references to an Article or Section include all subparts thereof.

20. Severability. If any provision of this Agreement, or the application thereof to any person, place or circumstance, shall be held by a court of competent jurisdiction to be invalid, unenforceable or void, the remainder of this Agreement and such provisions as applied to other persons, places and circumstances shall remain in full force and effect only if, after excluding the portion deemed to be unenforceable, the remaining terms shall provide for the consummation of the transactions contemplated hereby in substantially the same manner as originally set forth at the later of the date this Agreement was executed or last amended.

21. Third Party Beneficiaries. No provision of this Agreement shall create any third party beneficiary rights in any person.

[Signature pages follow.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the day and year first above written.

Name: Aaron Finlay Title: Chief Financial Officer and Company Secretary

# HOLDERS' SIGNATURE PAGE

## TO THE

## REGISTRATION RIGHTS AGREEMENT

EXECUTED this day of	, 2006
SIGN HERE: X	
	Exact Number of Registrable Securities
-	Enter number of ADSs of pSivida Limited (other than Registrable Securities) that you own.
IF AN ENTITY, ADD:	
By: Title:	Have you or your organization had any position, office or other material relationship within the past three (3) years with pSivida Limited or its affiliates? Check one:
	[]Yes
ALL HOLDERS:	[ ] No
Address:	If "Yes" please describe:
Fax:	

EXHIBIT 4.12

#### EXECUTION COPY

[\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24B-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

AMENDED AND RESTATED

#### LICENSE AGREEMENT

#### BETWEEN

#### CONTROL DELIVERY SYSTEMS, INC.

AND

#### BAUSCH & LOMB INCORPORATED

THIS AGREEMENT IS CONFIDENTIAL AND SHALL NOT BE DISCLOSED TO ANY THIRD PARTY EXCEPT IN ACCORDANCE WITH THE PROCEDURES SPECIFIED IN ARTICLE 32 HEREOF.

Dated as of December 9th, 2003

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Exhibit 16.2(iii)	-	Exceptions to Ownership of Licensed Patents
Exhibit 16.2(v)	-	Licensor Disclosees
Exhibit 36.1A	-	Clinical Agreements
Exhibit 36.1B	-	Trial Agreements

#### AMENDED AND RESTATED LICENSE AGREEMENT

THIS AMENDED AND RESTATED LICENSE AGREEMENT ("Agreement"), effective as of the 9th day of December, 2003 (the "Amendment Date"), is made between Control Delivery Systems, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 400 Pleasant Street, Watertown, Massachusetts 02472-2234 ("Licensor") and Bausch & Lomb Incorporated, a corporation organized and existing under the laws of the State of New York and having its principal place of business at One Bausch & Lomb Place, Rochester, New York 14604 ("Licensee"). Collectively, Licensor and Licensee are "Parties" and, individually, a "Party."

#### RECITALS

WHEREAS, the Parties have entered into, and performed in part under, the License Agreement between Licensor and Licensee, dated June 9, 1999, as amended January 1, 2001, December 31, 2001, and April 14, 2003 (the "1999 Agreement"), and the License and Development Agreement dated December 31, 1992, between Licensor and Licensee, as the assignee of ChironVision Corporation (formerly Chiron IntraOptics, Inc.) ("Chiron"), as amended August 16, 1993, March 30, 1995, June 23, 1995, and December 31, 1997 (the "Vitrasert Agreement"); and

WHEREAS, the Parties have determined to change, in part, the nature of their relationship with respect to the development, manufacturing and licensing of products under the 1999 Agreement and with respect to intellectual property rights and other matters reflected in this Agreement; and

WHEREAS, the Parties wish to amend and restate their intentions into a single agreement, all to effect the foregoing changes.

NOW THEREFORE, in consideration of the mutual promises set forth below, the Parties agree as follows:

#### ARTICLE 1. DEFINITIONS:

In addition to the terms defined elsewhere in this Agreement, the following terms shall have their associated meanings.

1.1 Active Commercialization or Actively Commercializing. "Active Commercialization" and "Actively Commercializing" means: (a) Licensee diligently conducting clinical trials for Uveitis Base Royalty Product; or (b) with respect to a Uveitis Base Royalty Product for which clinical trials are complete, Licensee diligently obtaining Regulatory Approval; or (c) with respect to a Uveitis Base Royalty Product that has received Regulatory Approval in one or more markets, Licensee diligently Commercializing such product in such markets; all in active furtherance of Licensee's diligence obligations pursuant to Articles 5 and 6 of this Agreement.

1.2 Affiliate. "Affiliate" of any Party means any Person that is controlled by, controls, or is under common control with such Party, for so long as such control relationship continues to exist. "Control" as used in this definition means the possession, directly or indirectly, of the power to direct or cause the direction of the management of a Person, whether through ownership of voting securities, by contract, or otherwise.

1.3 Amendment Date. "Amendment Date" shall mean December 9th, 2003.

1.4 ANDA. "ANDA" means an Abbreviated New Drug Application and all associated documents and components thereof, required to be filed with the FDA in order to obtain approval to market a particular product in the United States.

1.5 ARMD. "ARMD" means age-related macular degeneration.

1.6 Base Royalty. "Base Royalty" means a running royalty rate of [\*] of Net Sales, provided that, as set forth in Section 3.8, the amount of royalties due and owing pursuant to Section 3 shall be subject to Licensee's right of recoupment as follows: if the Advanced Amount has not been fully repaid by Licensor to Licensee as required hereunder, the amount of any royalties that might otherwise be due and owing from Licensee to Licensor under this Agreement shall in all instances be the amount determined in accordance with Article 3, less the Unpaid Advanced Amount at the time of such determination.

1.7 Clinical IP. "Clinical IP" means (i) all pre-clinical and clinical protocols, studies, data and results and study-related forms, materials and reports (e.g., investigator brochures, informed consent forms, data safety monitoring board related documents, patient recruitment related materials, biocompatibility studies, animal studies, safety studies, and chemistry, manufacturing and control data) used in or resulting from any pre-clinical or clinical study or trial and any audits of any pre-clinical or clinical study or trial of any First Generation Exclusive Licensed Product or the Vitrasert Licensed Product in the Licensed Field, and (ii) all INDs, NDAs, any unfiled applications, components or materials normally associated with an IND or NDA, regulatory filings or applications comparable to INDs or NDAs in any foreign jurisdictions, and other regulatory applications and approvals regarding any First Generation Exclusive Licensed Product or the Vitrasert Licensed Field.

1.8 Commercialize, Commercializing or Commercialization. "Commercialize", "Commercializing" or "Commercialization" means the sale, offering for sale, distribution, or marketing, of a product.

1.8 A Co-Owned Patents. "Co-Owned Patents" is defined in Section 2.8 of this Agreement.

1.9 Confidential Information. "Confidential Information" is defined in Article 32 of this Agreement.

1.10 Develop, Developing or Development. "Develop", "Developing" or "Development" means performance of human clinical trials for a product.

1.11 DME. "DME" means diabetic macular edema.

1.12 DR. "DR" means diabetic retinopathy.

 $[\star]$  - INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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1.13 Eligible Licensed Product. "Eligible Licensed Product" is defined in Section 3.2 of this Agreement.

1.14 First Generation Exclusive Licensed Product. "First Generation Exclusive Licensed Product" shall mean a product, other than the Vitrasert Licensed Product, that is an implant that is required to be surgically inserted through an incision of at least 2 mm (and which cannot be inserted through an incision of the eye, cannot be injected, and uses a reservoir design that generally conforms to the drawings and specifications (and any prior iterations thereof in whole or in part) shown in Exhibit 1.14. An example of such a design is that which is currently used in clinical trial #005 and #002 for DME and clinical trial #001 for Uveitis.

1.15 FDA. "FDA" means the United States Food and Drug Administration.

1.16 Generic Product. "Generic Product" is defined in Section 3.2 of this Agreement.

1.17 Improvement. "Improvement" means any Invention which is a development, enhancement, improvement, invention, modification, derivative or new use of a Licensed Product, [\*].

1.18 IND. "IND" means an Investigational New Drug Application and associated documents, components thereof, or corresponding applications and associated documents for devices or combination products, required to be filed with the FDA in order to obtain approval to commence human clinical trials of product in the United States.

1.19 Invention. "Invention" shall mean any invention or discovery.

1.20 Issued Patent Claim. "Issued Patent Claim" is defined in Section 1.50 of this Agreement.

1.21 Know-how. "Know-how" means unpatented information, whether or not patentable, including, without limitation, technical information, processes, formulae, trade secrets, materials, designs, drawings and data.

1.22 Licensed Field. "Licensed Field" means with respect to: (a) the First Generation Exclusive Licensed Products, any and all use for the treatment, prevention and/or diagnosis of any disease, disorder and/or condition of the human eye; (b) Non-Exclusive Licensed Products, any and all use for the treatment, prevention and/or diagnosis in humans of [\*] (c) Vitrasert Licensed Product, any and all use for the prevention and treatment of cytomegalovirus retinitis in humans; and (d) all Licensed Products, any and all research in non-human eyes.

1.23 Licensed Patents. "Licensed Patents" shall mean all: (1) patents issued to or licensed by Licensor on or before June 18, 2003, as set forth in Exhibit 1.23(a), other than those specific patents listed on Exhibit 1.23(b); (2) patent applications filed by Licensor on or before June 18,

 $[\star]$  - INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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2003, as set forth in Exhibit 1.23(a), other than those specific patent applications listed on Exhibit 1.23(b); (3) patent applications filed by Licensor after June 18, 2003, to the extent directed to the specific inventions made before June 18, 2003, and disclosed in the invention disclosure forms set forth in Exhibit 1.23(a), other than those specific invention disclosure forms listed on Exhibit 1.23(b); and (4) all patents and patent applications claiming priority to the patents or patent applications set forth in (1) - (3) above, including (i) any continuation, continuation-in-part (to the extent the claims are specifically directed to the subject matter in the patent or patent application to which it claims priority), divisional, reissue, reexamination, or renewal with respect to any of the foregoing, and (ii) any corresponding patent, utility model, inventor certificate, registration or the like in any country of the world with respect to the foregoing; provided, however, that notwithstanding anything to the contrary in this Section 1.23 or elsewhere in this Agreement, Licensed Patents shall not include any patent or patent application, or any claim thereof, that is directed to inventions made by Licensor after June 18, 2003. Exhibit 1.23(a) shall be updated from time to time by Licensor to incorporate the patent application serial numbers for the patent applications referenced in subsection (3) above. For the purposes of this Section 1.23, patents, patent applications, Patent Rights and Inventions shall only mean patents, patent applications, Patent Rights and Inventions of Control Delivery Systems, Inc., and shall not include patents, patent applications, Patent Rights and Inventions of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Control Delivery Systems, Inc., or a third party acquiror or transferee of substantially all of the assets or stock of Control Delivery Systems, Inc.'s opthalmics business.

1.24 Licensed Product. "Licensed Product" means First Generation Exclusive Licensed Product, Vitrasert Licensed Product, and Non-Exclusive Licensed Product.

1.25 Licensed Territory. "Licensed Territory" means the world.

1.26 Licensee Improvement. "Licensee Improvement" is defined in Section 8.3(a) of this Agreement.

1.27 Licensee Improvement Application. "Licensee Improvement Application" is defined in Section 8.3(a) of this Agreement.

1.28 Licensee Improvement Patent. "Licensee Improvement Patent" is defined in Section 8.3(b) of this Agreement.

1.29 Licensor Improvement Product. "Licensee Improvement Product" is defined in Section 8.3(b) of this Agreement.

1.29A Licensor Improvement. "Licensor Improvement" means any Improvement created, invented or discovered by Licensor, after June 18, 2003 and before [\*], provided, however, that in the event of (i) any transfer by Licensee of substantially all of the assets or stock of Licensee's proprietary (branded and/or generic) ophthalmic pharmaceutical business; or (ii) any transfer by Licensor of substantially all of the assets or stock of Licenser's proprietary consistent of substantially all of the assets or stock of Licensee's proprietary (branded and/or generic) ophthalmic pharmaceutical business; or (ii) any transfer by Licensor of substantially all of the assets or stock of Licensor's ophthalmics business, "Licensor Improvement" shall only include Improvements created, invented or discovered by Licensor after June 18, 2003 and before the earlier of (x) the effective date of such transfer or (y) [\*]. For the purposes of this Section 1.29A,

 $[\,\star\,]\,-$ INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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Improvements shall only mean Improvements of Control Delivery Systems, Inc., and shall not include Improvements of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Control Delivery Systems, Inc., or a third party acquiror or transferee of substantially all of the assets or stock of Control Delivery Systems, Inc.'s opthalmics business.

1.29B Licensor Improvement Patents. Any patent application filed by Licensor to the extent it claims a Licensor Improvement, and any issued patents or patent applications to the extent they claim priority thereto.

1.30 Milestone Payment. "Milestone Payment" is defined in Article 4 of this Agreement.

1.31 NDA. "NDA" means a New Drug Application and all associated documents, components thereof, or corresponding applications and associated documents for devices or combination products, required to be filed with the FDA in order to obtain approval to market a particular product in the United States.

1.32 Net Sales. "Net Sales" means, in any case where a Licensed Product is sold or commercially disposed of for value by Licensee or any Sublicensee in an arm's length transaction with a third party (other than an Affiliate of, respectively, Licensee or Sublicensee), the gross invoice price for such Licensed Product, less the following: (i) discounts, chargebacks, Medicare or other government rebates, and rebates to purchasers actually taken or allowed; (ii) credits or allowances given or made for rejections or return of any previously sold Products actually taken or allowed; (iii) to the extent included in such gross invoice price any tax or government charge imposed on the production, import, export, sale, delivery or use of such Products, including, without limitation, any value added or similar tax or government charge, but not including any tax levied with respect to income; and (iv) to the extent included in such gross invoice price any reasonable and documented packaging and distribution charges. Net Sales shall also include and be deemed to have been made with respect to (a) any Licensed Product not sold or otherwise transferred to any third party but rather used by Licensee or any Sublicensee to provide a commercial service and (b) any other transfer of a Licensed Product for less than arm's length value other than intercompany transfers where the transferee is not the end user. The amount of any Net Sale as defined in the preceding sentence shall be imputed using the price or prices at which the Licensed Product at issue is then being sold in transactions covered by the first sentence of this Section or, if no such transactions have occurred, on a reasonable basis to be determined at the time by the Parties. Notwithstanding any other provision of this Section, Net Sales shall not include the transfer without consideration of any Licensed Product by Licensee or any Sublicensee (x) for use in any clinical trial or in any preclinical or other research, (y) as detailing samples or other use to promote additional Net Sales in amounts consistent with the normal business practices of Licensee or any Sublicensee, or (z) for compassionate use.

1.33 Non-Exclusive Licensed Product. "Non-Exclusive Licensed Product" means a product (a) that meets the following criteria: (i) uses as its active ingredient only one or more of the active ingredients set forth in column A of Exhibit 1.33, and no others, and (ii) uses one of the delivery systems in column B of Exhibit 1.33, and (iii) uses one of the methods of delivery set forth in column C of Exhibit 1.33; and (iv) uses one of the anchoring methods set forth in

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column D of Exhibit 1.33; and (v) is applied in one of the locations set forth in column E of Exhibit 1.33; and (vi) is approved, or is designed to be approved, for the treatment of one or more of the indications set forth in Column F of Exhibit 1.33, and no others; and (b) the manufacture, use, sale, offering for sale or importing of which, absent the license granted by Licensor to Licensee herein, would infringe any Valid Claim included in any Licensed Patent or Licensor Improvement Patent. Notwithstanding the foregoing, Non-Exclusive Licensed Product shall exclude First Generation Exclusive Licensed Product.

1.34 Original Effective Date. "Original Effective Date" means December 31, 1992, for rights and obligations hereunder related to Vitrasert Licensed Product and June 9, 1999, for all other rights and obligations hereunder.

1.35 Other Technology. "Other Technology" means Patent Rights owned or controlled by Licensor and not included as a Licensed Patent or Licensor Improvement Patent.

1.36 Patent Rights. "Patent Rights" means any and all forms of patents issued or granted anywhere in the world, including, without limitation, utility, model and design patents, patents of addition, patents of importation or innovation, improvement patents, reissued and reexamined patents, all renewals and extensions thereof, and all applications for such patents (including original, divisional, continuation and continuation-in-part applications) pending before any national Patent Office and which have not been abandoned or expired.

1.37 Person. "Person" means any individual, partnership, association, corporation, trust, or other legal person or entity.

1.38 Regulatory Approval. "Regulatory Approval" means (a) approval by the FDA of an NDA and satisfaction of any related applicable FDA requirements (if any) or (b) in any country other than the United States, approval by regulatory authorities having jurisdiction over such country of a single application or set of applications comparable to an IND, NDA, and satisfaction of any related applicable regulatory and notification requirements, if any, together with any other approvals necessary to make and sell pharmaceuticals or delivery systems in such country.

1.39 Right of Access to Clinical IP. "Right of Access to Clinical IP" means the right to reference, cross-reference, review, have access to, incorporate and use Clinical IP in any regulatory, applications or filings or for any research or development purpose.

1.40 Sublicense. "Sublicense" means any sublicense of, or other agreement permitting the commercial exploitation of, some or all of the rights granted to Licensee under this Agreement.

1.41 Sublicensee. "Sublicensee" means any  $\ensuremath{\mathsf{Person}}$  to whom  $\ensuremath{\mathsf{Licensee}}$  grants a Sublicense.

1.42 Target Market. "Target Market" means each of the [\*].

1.43 Term of this Agreement. "Term of this Agreement", "term of this Agreement", or "Term" shall mean the period beginning on the Original Effective Date and continuing only for so long as (a) Licensee has any right to exercise any of its rights with respect to any Licensed Patent or Licensor Improvement Patent in the Licensed Territory, or (b) royalty payments are

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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due under this Agreement, unless earlier terminated by Licensor or Licensee as provided herein.

1.44 Third Party Licensed Product. "Third Party Licensed Product" means a First Generation Exclusive Licensed Product or a Non-Exclusive Licensed Product, the therapeutic effect of which is derived in part from any proprietary product, compound, method or process in-licensed or acquired by Licensee from an unaffiliated third party on an arm's length basis; provided that such First Generation Exclusive Licensed Product or Non-Exclusive Licensed Product is subject to a running royalty equal to the Base Royalty.

1.44A Third Party Licensor Improvement Product. "Third Party Licensor Improvement Product" is defined in Section 8.3(d) of this Agreement.

1.45 Total Relevant Sales. "Total Relevant Sales" is defined in Section 3.2 of this Agreement.

1.46 UKRF. "UKRF" means University of Kentucky Research Foundation.

1.47 UKRF Licenses. "UKRF Licenses" mean the licenses set forth in Exhibit 1.47.

1.48 Uveitis Base Royalty Product. "Uveitis Base Royalty Product" means a Uveitis Product the Net Sales of which bear, or for a product that has not yet received Regulatory Approval, will bear, the Base Royalty payable to Licensor that is not subject to any royalty reduction or offset under this Agreement.

1.49 Uveitis Product. "Uveitis Product" means any product which has received or is designed to receive Regulatory Approval to treat Uveitis.

1.50 Valid Claim. "Valid Claim" means (i) a claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealed or unappealable within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise (an "Issued Patent Claim"), and/or (ii) a pending claim of any pending patent application which has been filed and continues to be prosecuted in good faith and is not abandoned or finally disallowed without the possibility of appeal or refiling (a "Pending Claim"); provided, however, that, with respect to any Licensed Product or Licensor Improvement Product, no Pending Claim which has not become an Issued Patent Claim shall continue to constitute a Valid Claim for more than five years following the first approved commercial sale of the first Licensed Product or Licensor Improvement Product which qualifies as a Licensed Product or Licensor Improvement Product solely as a result of such Pending Claim.

1.51 Vitrasert Licensed Product. "Vitrasert Licensed Product" means the product that has received FDA regulatory approval pursuant to application #20-569 as approved on March 4, 1996, and the manufacture, use, sale, or importation of which would, absent the license granted by Licensor to Licensee herein, infringe any Valid Claim included in the Licensed Patents.

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### ARTICLE 2. GRANTING CLAUSE:

- 2.1 License Grant.
- 2.1.1 License to First Generation Exclusive Licensed Product and Vitrasert Licensed Product. Licensor grants to Licensee, and Licensee accepts, an exclusive, royalty-bearing, worldwide right and license, with exclusive right to sublicense, under Licensor's interest (i.e., subject to the UKRF Licenses) in the Licensed Patents and Licensor Improvement Patents, solely to make, have made, use, sell, offer to sell, and import First Generation Exclusive Licensed Products and Vitrasert Licensed Product in the Licensed Field.
- 2.1.2 License to Non-Exclusive Licensed Product. Licensor grants to Licensee, and Licensee accepts a non-exclusive, royalty-bearing, worldwide right and license, without the right to sublicense, under Licensor's interest (i.e., subject to the UKRF Licenses) in the Licensed Patents and Licensor Improvement Patents solely to make, have made (including by manufacturers), use, sell, offer to sell, have sold (including by distributors), and import Non-Exclusive Licensed Products in the Licensed Field.

2.1.3 Intentionally Omitted.

- 2.1.4 No License. Nothing in this Agreement shall be construed as granting a license, whether express, implied or by operation of law, to Licensee under any Patent Rights, Know-how, or other proprietary rights owned, acquired or controlled by Licensor other than the rights expressly granted by Licensor to Licensee in this Agreement, including, without limitation, Sections 2.3 and 2.8. Licensee shall have no rights in any Other Technology or in any inventions disclosed in any patents, patent applications or invention disclosure forms listed in Exhibit 1.23(b), regardless of whether such Other Technology or such inventions disclosed in Exhibit 1.23(b) incorporate, or are infringed by the use of, Licensor Know-how. This Agreement does not create, and shall under no circumstances be construed or interpreted as creating, an obligation on the part of Licensor to grant any license to Licensee agreement between the Parties shall be in writing.
- 2.1.5 Reserved Rights. All rights not expressly granted to Licensee in this Agreement are reserved to Licensor for itself, its partners and Affiliates (other than Licensee) and other licensees and sublicensees. Notwithstanding the licenses granted in Article 2, Licensor hereby retains and reserves a royalty-free right and license to use and permit others to use the Licensed Patents and Licensor Improvement Patents for research, but not for making, using, selling, or importing any commercial products or processes for First Generation Exclusive Licensed Products and the Vitrasert Licensed Product, and for development purposes, subject in all cases to Section 2.5.

2.2 Sublicensing. Licensee shall have the right to grant Sublicenses under the license granted pursuant to Section 2.1.1, provided, however, that any such Sublicense shall not be inconsistent with the terms and conditions of this Agreement and that Licensee shall be responsible for the operations of any Sublicensee relative to this Agreement as if such operations were carried out by Licensee itself, including (without limitation) the payment of any royalties provided for

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hereunder, regardless of whether the terms of any Sublicense provide for such amount to be paid by the Sublicensee directly to Licensor, but Sublicensees shall not be required to pay Milestones Payments pursuant to Article 4.

2.3 Non-suit. While the licenses granted hereby only include rights to Licensed Patents and Licensor Improvement Patents as expressly stated in this Agreement, and do not include rights to Other Technology, Licensor shall not bring (and shall not authorize or assist a third party to bring) any action under Other Technology owned by Licensor or controlled and able to be licensed by Licensor to block Licensee or any Sublicensee from:

(a) exercising its rights with respect to a Uveitis Base Royalty Product that is an implant that is required to be surgically inserted through an incision of at least 2 mm (and which cannot be inserted through an incision of less than 2 mm) in the scelera into the vitreous, is secured by a suture attaching a tab to the scelera in the posterior of the eye, uses the reservoir/suture tab design currently used in clinical trial #001 for Uveitis, uses fluocinolone acetonide as an active ingredient with no other active ingredients, and generally conforms with the drawings and meets the specifications shown in Exhibit 1.14 of this Agreement and any prior iterations thereof, with only such modifications to the design that do not modify the parameters set forth above and that are required to obtain Regulatory Approval for the implant in the above clinical trials as a result of the current stability issue or another safety issue that may arise during the course of such clinical trials; and

(b) exercising those rights (but only those rights) granted by Licensor to Licensee pursuant to Section 2.1.1, provided that:

(i) the Other Technology is filed on or before or claims priority to an application filed on or before December 31, 2004 (provided the non-suit only applies to the extent of claims directed to the subject matter in the application to which such Other Technology claims priority); and

(ii) the Other Technology claims an invention for which Licensee, prior to any public disclosure of the Invention by the Licensor, has recorded an invention disclosure form including one or more claims to the same Invention, provided that such invention disclosure form has described such Invention with enough particularity to demonstrate that Licensee was in possession of the Invention at the time such invention disclosure form was recorded.

For the purposes of this Section 2.3, Other Technology shall not include those patents, patent applications and invention disclosure forms set forth in Exhibit 2.3 (i.e., Licensor shall not be precluded from bringing an action based on those patents, patent applications and invention disclosure forms set forth in Exhibit 2.3). Also, for the purposes of this Section 2.3, the non-suit granted herein shall not preclude Licensor from enforcing any of its rights in Other Technology that are directed to the composition of active ingredients, formulations, indications or novel polymers that are not limited in use or application to First Generation Exclusive Licensed Products. For the purposes of this Section 2.3, patents, patent applications, Patent Rights, Inventions and Other Technology shall only mean patents, patent applications, Inc., and shall not include

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patents, patent applications, Patent Rights, Inventions and other technology of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Control Delivery Systems, Inc., or a third party acquiror or transferee of substantially all of the assets or stock of Control Delivery Systems, Inc.'s opthalmics business. The provisions of this Section 2.3 shall in no way limit Licensee's rights under Licensor Improvement Patents as set forth in this Agreement.

2.4 Non-assert of Know-how. Licensor shall not bring (and shall not authorize or assist a third party to bring) any action against Licensee or a Sublicensee alleging misappropriation of Licensor's Know-how. Licensee shall not bring (and shall not authorize or assist a third party to bring) any action against Licensor or a sublicensee of Licensor alleging misappropriation of Licensee's Know-how. For the purposes of this Section, Licensor's Know-how shall be limited to Know-how known by Licensor as of June 18, 2003, and Licensee's Know-how shall be limited to Know-how known by Licensee as of June 18, 2003. The prohibitions of this Section shall not apply to any action which the aggrieved Party may bring if such action is limited to the intentional and willful theft or misappropriation of the Know-how based on misappropriation actions occurring by the other Party solely after the Amendment Date. For the purposes of this Section 2.4, Know-how shall only mean Know-how of Control Delivery Systems, Inc., and shall not include Know-how of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Control Delivery Systems, Inc., or a third party acquiror or transferee of substantially all of the assets or stock of Control Delivery Systems, Inc.'s opthalmics business.

### 2.5 Non-Compete.

(a) Non-Compete for Uveitis Product. Licensor shall not Develop, or license a third party to Develop, a Uveitis Product, but only for so long as (1) Licensee is Actively Commercializing a Uveitis Base Royalty Product; and (2) Licensee is not Developing or Commercializing a Uveitis Product that is not a Uveitis Base Royalty Product. Licensor further agrees not to Commercialize, or license a third party to Commercialize, a Uveitis Product but only for so long as (3) Licensee is Actively Commercializing a Uveitis Base Royalty Product; and (4) Licensee is not Commercializing a Uveitis Product that is not a Uveitis Base Royalty Product. Notwithstanding the foregoing, the prohibitions under this Section 2.5(a) shall not apply to the Development and Commercialization activities of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Licensor, or a third party acquiror or transferee of substantially all of the assets or stock of Licensor's opthalmics business, provided that such acquiror, acquiree, transferor, transferee, or a merger or consolidation partner does not use in such Development or Commercialization activities for a Uveitis Product any (i) Licensed Patent or (ii) Know-how owned or controlled by Licensor as of the date of such acquisition, transfer, merger or consolidation. For the purposes of this Section 2.5(a), patents, patent applications, Patent Rights, Inventions and Know-how shall only mean patents, patent applications, Patent Rights, Inventions and Know-how of Control Delivery Systems, Inc., and shall not include patents, patent applications, Patent Rights, Inventions and Know-how of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Control Delivery Systems, Inc., or a third party acquiror or transferee of substantially all of the assets or stock of Control Delivery Systems, Inc.'s opthalmics business. In addition, the Parties

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agree that whenever Licensee realizes revenue from Commercializing a Uveitis Product, Licensee will receive a royalty on such revenue.

Licensee shall provide written notice to Licensor within ninety (90) days after: (x) Licensee's filing of an IND for a Uveitis Product that is not a Uveitis Base Royalty Product; (y) Licensee's ceasing to Actively Commercialize a Uveitis Base Royalty Product; and (z) Licensee's Commercialization of a Uveitis Product that is not a Uveitis Base Royalty Product. Such written notice shall set forth in reasonable detail the basis for Licensee's determination of whether a Uveitis Product is or is not a Uveitis Base Royalty Product.

If Licensee no longer satisfies the requirements of Sections 2.5(a)(1), (2), (3) or (4) and Licensor has commenced animal pre-clinical trials, the restrictions of this Section 2.5 shall no longer be applicable to Licensor and shall thereafter terminate, regardless of whether Sections 2.5(a)(1), (2), (3) or (4) are subsequently satisfied by Licensee. Notwithstanding the foregoing, Licensor shall not be prohibited under this Section from Developing or Commercializing a product designed and approved for an indication other than Uveitis, regardless of whether such product is or could be subject to off-label or other unapproved sales or uses for the prevention, treatment or diagnosis of Uveitis.

(b) Non-Compete for First Generation Exclusive Licensed Product. Licensor agrees that during the Term of this Agreement, Licensor shall not Develop or Commercialize a First Generation Exclusive Licensed Product so long as Licensee has exclusive rights to such First Generation Exclusive Licensed Product under this Agreement. Notwithstanding the foregoing, the prohibitions under this Section 2.5(b) shall not apply to the Development or Commercialization activities of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Licensor, or a third party acquiror or transferee of substantially all of the assets or stock of Licensor's opthalmics business, provided that such acquiror, acquiree, transferor, transferee, or a merger or consolidation partner does not use in such Development or Commercialization activities for a First Generation Exclusive Licensed Product any (i) Licensed Patent or (ii) Know-how owned or controlled by Licensor as of the date of such acquisition, transfer, merger or consolidation. In consideration of the non-compete as set forth in this Section 2.5(b), as well as all other rights granted and information provided by Licensor to Licensee under this Agreement with respect to First Generation Exclusive Licensed Products, including without limitation the rights granted pursuant to Sections 2.1.1, 2.2, 2.3, 2.4, 2.5 and 2.6 herein, the Parties agree that the royalty rate set forth in Section 3.1.1 reflects the value of all such rights granted and information provided and shall be paid whether or not such First Generation Exclusive Licensed Product is covered by a Valid Claim in the Licensed Patents or Licensor Improvement Patents, and whether or not such royalty payments under Section 3.1.1 extend beyond the term of any Licensed Patent or Licensor Improvement Patent containing Valid Claims covering such First Generation Exclusive Licensed Product. For the purposes of this Section 2.5(b), patents, patent applications, Patent Rights, Inventions and Know-how shall only mean patents, patent applications, Patent Rights, Inventions and Know-how of Control Delivery Systems, Inc., and shall not include patents, patent applications, Patent Rights, Inventions and Know-how of a third party acquiree or transferor, or a third party merger or consolidation partner, of or with Control Delivery Systems, Inc., or a third party acquiror or transferee of substantially all of the assets or stock of Control Delivery Systems, Inc.'s opthalmics business.

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2.6 Licensor Disclosure of Inventions. Licensor represents that the patents, patent applications and invention disclosure forms listed on Exhibits 1.23(a) and (b) disclose all Inventions conceived or made by or on behalf of Licensor prior to June 18, 2003. Licensor agrees that any Invention conceived or made by or on behalf of Licensor prior to June 18, 2003, which is not listed on Exhibits 1.23(a) or (b) shall be deemed a Licensed Patent and added to Exhibit 1.23(a). For the purposes of this Section 2.6, patents, patent applications, Patent Rights and Inventions of Control Delivery Systems, Inc., and shall not include patents, patent applications, Patent Rights or transferor, or a third party merger or consolidation partner, of or with Control Delivery Systems, Inc., or a third party acquiror or transferee of substantially all of the assets or stock of Control Delivery Systems, Inc.'s opthalmics business.

2.7 Licensee Disclosure of Inventions. Licensee represents that all Inventions conceived or made by or on behalf of Licensee after June 9, 1999, and before June 18, 2003, that: (a) directly relate to (i) treatment by (A) intraocular local delivery of an active ingredient into the eye, (B) local delivery of an active ingredient into the eye by injection into the scelera (provided that the foregoing in subparts (A) and (B) shall not include technology developed for the cataract, refractive surgical and contact lens businesses of Licensee), (ii) non-topical sustained ophthalmic release of an active ingredient (provided that the foregoing in this subsection (ii) shall not include technology developed for the cataract, refractive surgical and contact lens businesses of Licensee), (iii) co-drug modifications for altering the bioavailability or rate of release of a drug, where "co-drug" is defined as two or more pharmaceutically active ingredients that are linked by a covalent or ionic bond with each other, which bond dissolves in vivo, and where "co-drug" specifically excludes any natural extracts; or (iv) pro-drug modifications for altering the bioavailability or rate of release of a drug for non-topical applications; or (b) would interfere with the subject matter of, or dominate the practice of any invention disclosed in, Licensed Patents or invention disclosure forms disclosed in Exhibits 1.23(a) or (b) (all such inventions in subparts (a) and (b) of this Section 2.7 are referred to collectively as "Licensee Relevant Inventions") are disclosed in the invention disclosure forms and unpublished patent applications that have been disclosed to Licensor's counsel by Licensee. In addition to any other remedies available to Licensor, Licensee shall grant and hereby grants Licensor a world-wide perpetual, non-exclusive royalty-free license, with the right to sublicense, to use any Licensee Relevant Invention made by Licensee after June 9, 1999, and before June 18, 2003, that was not disclosed to Licensor's counsel by Licensee; provided, however, that such right and license shall be subject to Licensee's other rights hereunder, e.g., the exclusive rights granted under Section 2.1.1 and Section 2.5.

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2.8 Co-Owned Patents. With respect to the patents and patent applications listed in Exhibit 2.8 and any inventions disclosed in the invention disclosure forms listed in Exhibit 2.8, including all Patent Rights in the foregoing (the "Co-Owned Patents"), Licensee shall assign and hereby assigns to Licensor a one-half interest in the Co-Owned Patents, and to the extent of Licensor's interest in the Co-Owned Patents, such Co-Owned Patents shall be deemed to be Licensed Patents, provided that Licensor's interest in the Co-Owned Patents shall be exclusively licensed to Licensee solely to make, have made, use, sell, offer to sell, and import Licensed Products in the field of ophthalmology, and further provided that such license shall (a) become non-exclusive in the event Licensee's rights to First Generation Exclusive Licensed Product become non-exclusive; and (b) terminate in the event this Agreement terminates. Licensee shall fully cooperate with Licensor, at Licensor's expense, with any activities necessary to perfect the rights assigned to Licensor, including the execution of assignments of any patents or patent applications or the filing of any patent applications.

2.9 Licensee Non-suit. Licensee shall not bring (and shall not authorize or assist a third party to bring) any action under any patents or patent applications listed in Exhibit 2.9 or any Inventions disclosed in the invention disclosure forms listed in Exhibit 2.9, including all Patent Rights or other intellectual property rights in the foregoing, against Licensor or any sublicensee of Licensor.

2.10 Licensee Covenant Not to File. Licensee shall not file (and shall not authorize or assist an Affiliate or other third party to file) an application for Patent Rights, either in the United States or in any other foreign jurisdiction, containing claims covering any inventions disclosed in the invention disclosure forms listed in Exhibit 2.10.

2.11 Frustration Regarding Vitrasert Product. Subject to the last sentence of Section 14.1 of this Agreement, if any third party brings any cause of action, claim, or other challenge which has the result of frustrating in a material way the licensing of the intellectual property applicable to Licensee's rights with respect to the Vitrasert Licensed Product (a "Frustration Claim"), Licensor shall cooperate with Licensee in any reasonable arrangement designed to give Licensee as nearly as possible the same economic benefits with respect to a Vitrasert Licensed Product and to have Licensee assume the same obligations and expenses as if such Frustration Claim with respect to a Vitrasert Licensed Product had not occurred.

ARTICLE 3. ROYALTIES AND REPAYMENT OBLIGATIONS

- 3.1 Running Royalties. Licensee shall pay running royalties to Licensor as follows:
- 3.1.1 Net Sales of First Generation Exclusive Licensed Products. Subject to Sections 3.2 and 3.3, on all Net Sales of First Generation Exclusive Licensed Products, Licensee shall pay to Licensor a running royalty rate equal to the Base Royalty.
- 3.1.2 Net Sales of Third Party Licensed Products. Subject to Section 3.3, on all Net Sales of any Third Party Licensed Product Licensee shall pay to Licensor a running royalty equal to the Base Royalty reduced by [\*] of the amount of any running royalty payable or "deemed paid or payable" by Licensee with respect to such Net Sales to any third party licensor of proprietary technology or other proprietary property included in such Third

 $[\,\star\,]-\text{INDICATES}$  MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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Party Licensed Product, provided, however, that the total running royalty due to Licensor with respect to such Net Sales shall in no event be less than [\*] of the Base Royalty. Where Licensee acquires rights to a Third Party Licensed Product but doesn't pay a royalty based on net sales, units sold, etc., royalties "deemed paid or payable" shall be the imputed royalty paid by Licensee in connection with the payment of the purchase price or other consideration to acquire those rights needed to use the applicable proprietary product, compound, method, or process in such Third Party Licensed Product. Where Licensee acquires rights to such proprietary product, compound, method or process which permit Licensee to use such product, compound, method or process for purposes other than use in connection with such Third Party Licensed Product or where Licensee acquires the applicable proprietary product, compound, method or process in connection with the acquisition of any other rights or assets, a reasonably allocable share of such purchase price or other consideration shall be allocated to the right to use such product, compound, method or process in connection with such Third Party Licensed Product. The allocated portion of the purchase price or other consideration shall then be converted into an imputed royalty, taking into account all relevant factors, including, without limitation, the length of time over which Licensee may exercise the rights involved, the likely sales of such Third Party Licensed Product over such period of time, and/or other factors considered relevant at the time. In no event shall the deemed royalty so derived exceed the royalty that would have been paid for the rights involved in an arms-length transaction with such third party had Licensee licensed such rights for use in connection with such Third Party Licensed Product on a purely royalty-bearing basis. If Licensor and Licensee cannot agree on the amount of any deemed royalty, the issue shall be resolved by the dispute resolution provisions of this Agreement.

- 3.1.3 Net Sales of Vitrasert Licensed Products. Subject to Section 3.3, on all Net Sales of Vitrasert Licensed Product, Licensee shall pay to Licensor a running royalty equal to [\*] of Net Sales. In addition to payment of the royalty under this Section 3.1.3, Licensee shall also pay to Licensor all amounts due to UKRF under the UKRF Licenses for Net Sales of Vitrasert Licensed Product.
- 3.1.4 Net Sales of Non-Exclusive Licensed Products. For Non-Exclusive Licensed Products, other than Third Party Licensed Products, Licensee shall pay to Licensor a running royalty rate equal to: (a) the Base Royalty on all Net Sales of Non-Exclusive Licensed Product employing a delivery system, which delivery system would, absent the license granted by Licensor to Licensee herein, infringe any Valid Claim included in a Licensed Patent or Licensor Improvement Patent; (b) [\*] of Net Sales of Non-Exclusive Licensed Product that employs an anchoring method, which anchoring method would, absent the license granted by Licensor to Licensee herein, infringe only a Valid Claim of a Licensed Patent or Licensor Improvement Patent related to the anchoring method, and that is not subject to payment of a running royalty pursuant to Section 3.1.4(a); and (c) a royalty rate to be determined by arbitration through the American Arbitration Association ("AAA") for any Non-Exclusive Licensed Product that is not subject to payment of a running royalty pursuant to Sections 3.1.4(a) or 3.1.4(b) and which would, absent the license granted by Licensor to Licensee herein, infringe any Valid Claim included in a Licensed Patent or Licensor Improvement Patent, provided that such rate shall be not less than [\*] of Net Sales and not greater than

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[\*] of Net Sales. For the purposes of the AAA arbitration, all Valid Claims included in any Licensed Patent or Licensor Improvement Patent shall be deemed valid and enforceable.

3.2 Royalty Step-Down for Generic Competition.

(a) Notwithstanding anything in this Agreement to the contrary, in each country where (i) the making, using, selling, offering to sell or importing of a particular Uveitis Base Royalty Product or a particular First Generation Exclusive Licensed Product does not infringe a Valid Claim of a Licensed Patent or a Licensor Improvement Patent; and (ii) such Uveitis Base Royalty Product or First Generation Exclusive Licensed Product is no longer covered under Hatch-Waxman, Orphan Drug, Pediatric, or other non-patent exclusivity, including applicable similar standards outside the United States; and (iii) with respect to First Generation Exclusive Licensed Product, such product is subject to a running royalty equal to the Base Royalty, and is not subject to a royalty reduction or offset, including without limitation an offset under Section 3.1.2 of this Agreement, then with respect to each such Uveitis Base Royalty Product or First Generation Exclusive Licensed Product (each an "Eligible Licensed Product") in such country, Licensee Shall be entitled to a royalty adjustment for each such Eligible Licensed Product as follows:

If sales of Generic Product (as defined in subsection (b) below) in a particular fiscal quarter are greater than [\*] of Total Relevant Sales (as defined in subsection (b) below) for a particular Eligible Licensed Product, then the running royalty on Net Sales of such Eligible Licensed Product in such fiscal quarter shall be [\*].

(b) For the purposes of this Section 3.2, "Generic Product" shall mean a product or products sold by a third party without a license from Licensor that has been approved under an ANDA pursuant to 21 U.S.C. Section 355(j) (or a substantially similar application or filing in jurisdictions outside the United States) that references safety and efficacy data of an Eligible Licensed Product. For the purposes of this Section 3.2, "Total Relevant Sales" shall mean, in a fiscal quarter, the total combined sales by all Persons, including Licensee or Sublicensees, of (i) all Generic Product (with respect to a particular Eligible Licensed Product); and (ii) the relevant Eligible Licensed Product.

(c) In the event of any adjustments to the running royalty pursuant to this Section 3.2, Licensee shall provide to Licensor written notice of such adjustment, along with reasonably detailed documentation (including market reports and other data) supporting Licensee's determination of the Total Relevant Sales. Such written notice and documentation shall be supplied to Licensor with any Royalty Reports due to Licensor pursuant to Section 7.1, and shall be subject to the record keeping and audit rights as set forth in Section 7.2. In addition, in the event Licensee has made an adjustment to the running royalty of a Uveitis Base Royalty Product pursuant to this Section 3.2 such that the running royalty for such Uveitis Base Royalty Product in a country is less than the Base Royalty for two consecutive fiscal quarters, then Licensor shall have the right, at its sole discretion, to Develop and Commercialize a Uveitis Product in such country, notwithstanding the provisions of Section 2.5(a).

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such Uveitis Base Royalty Product in such country is equal to the Base Royalty in subsequent fiscal quarters.

3.3 Royalties Payable Only Once. Licensee's obligation to pay royalties under this Article 3 shall be imposed only once at the highest applicable royalty rate, with respect to any Net Sale of any Licensed Product. Only a single royalty shall be due and payable by Licensee under this Agreement with respect to a Licensed Product regardless of whether the Licensed Product is covered by more than one claim of a Licensed Patent or Licensor Improvement Patent and in no event will such royalty exceed [\*].

3.4 Timing of Royalty Payments. Within thirty (30) days after the end of each fiscal quarter of Licensee, Licensee shall pay to Licensor the royalty payment due for each such quarter in U.S. dollars, provided, however, that solely with respect to any royalty payment due with respect to Net Sales made pursuant to Sections 1.32(a) or (b) herein, such thirty (30) day period may be extended to such longer period as Licensee may reasonably require, not to exceed ninety (90) days, to determine the amount of such Net Sales for such fiscal guarter. If a Sublicensee adjusts any of its Net Sales for any applicable quarter on account of misreported or late-reported Net Sales, Licensee shall promptly pay (or cause the Sublicensee to pay) any royalties due within 30 days after such adjustment. If Net Sales are in a currency other than U.S. Dollars, the sales shall be converted from the currency of the country in which the sales were made into U.S. Dollars at the month-end exchange rate for such currency for such sales made during such month as determined by Licensee in accordance with its standard accounting policies and procedures consistently applied during each of Licensee's fiscal quarters. If any royalty or other amount due Licensor is in a non-U.S. Dollar currency, and Licensee or any Sublicensee is prohibited from exporting that currency from that jurisdiction, Licensee or such Sublicensee shall pay an amount equal to the royalty or other amount due in such blocked currency into a bank account of Licensor's choice in such jurisdiction, and such deposit shall be deemed to be full satisfaction of Licensee and Sublicensee's obligation to make the applicable payment to Licensor.

3.5 Withholding Taxes. Licensee and Licensor shall use all commercially reasonable and legal efforts to reduce tax withholding on any payments to be made to Licensor hereunder. If Licensee concludes that, notwithstanding such efforts, tax withholding under the laws of any country is required with respect to any royalty payment to be made to Licensor under this Agreement, Licensee shall pay or cause its Sublicensee to pay any applicable withholding taxes imposed by any such political jurisdiction on such royalty payments, and the amount of any such payments shall be credited against Licensee's royalty obligation under this Agreement. Licensee shall promptly provide Licensor with, or promptly cause Licensor to be provided with, original receipts or other evidence sufficient to allow Licensor to obtain the benefits of any such tax withholding.

# 3.6 Intentionally Omitted.

3.7 Repayment of Advanced Amount. The Parties acknowledge that Licensee has made advances to Licensor (collectively, "Advanced Amount") totaling Ten Million Forty-Four Thousand Seven Hundred Nineteen Dollars (\$10,044,719), which are still outstanding under the 1999 Agreement immediately preceding the Amendment Date. The Parties stipulate that

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the Advanced Amount constitutes all known financial liabilities of the Parties under all prior agreements between the Parties, including without limitation the 1999 Agreement, and no other amounts are due to Licensee by Licensor except as set forth in this Agreement. The Parties also acknowledge that the Advanced Amount is liquidated and that Licensee's right to payment of the Advanced Amount will not be subject to invocation of the dispute resolution procedure under Article 22. The Advanced Amount will be repaid and reduced as described in this Section 3.7. Any remaining amounts due after such repayment and reduction shall be the "Unpaid Advanced Amount." In addition, the Parties acknowledge that Licensor has provided services to Licensee between June 18, 2003, and the Amendment Date, for which Licensee will reimburse Licensor \$250,000. The reimbursement of the \$250,000 will be accomplished by reducing the Advanced Amount by \$250,000 such that the Unpaid Advanced Amount hereby is reduced to \$9,794,719. Licensor will repay, and, in addition to any other rights provided at law or equity, Licensee may recoup, such Unpaid Advanced Amount as follows:

- 3.7.1 Cash Payment. Licensor will pay Three Million Dollars (\$3,000,000) to Licensee in cash promptly upon the execution of this Agreement. Licensor will wire transfer such amount to Licensee pursuant to Licensee's instructions, and this Agreement will not be effective until Licensee has actually received such payment. This payment shall reduce the Unpaid Advanced Amount.
- 3.7.2 Milestone/Royalty Recoupment. After the reduction described in the first paragraph of Section 3.7 and the payment described in Section 3.7.1, the Unpaid Advanced Amount will be reduced to \$6,794,719. Licensee may further recoup the Unpaid Advanced Amount from (i) any Milestone Payments (as defined in Section 4.1), and (ii) royalty payments otherwise due Licensor hereunder in each case until the entire remaining Unpaid Advanced Amount has been fully repaid.
- 3.7.3 Equity Option. Licensor may make an optional payment of \$1,000,000 (One Million Dollars) to Licensee by December 27, 2003, which payment, if made, shall reduce the Unpaid Advanced Amount. Effective upon such payment, Licensee shall grant to Licensor an option to acquire all of Licensee's holdings of Licensor's common stock (600,000 shares, collectively the "Stock") at an exercise price of \$5.00 per share. This option must be in the form of Exhibit 3.7.3, and Licensee shall deliver the option certificate evidencing the option within 5 days of the payment that reduces the Unpaid Advanced Amount. Payments to Licensee as a result of exercising the option will not reduce the remaining Unpaid Advanced Amount, if any. The foregoing per share option price is not intended by the Parties to in any way represent the fair market value of such shares, and shall in no way be used by either Party to support a valuation of Licensor.
- 3.7.4 July 1, 2007. Irrespective of any other circumstances whatsoever, the Unpaid Advanced Amount, if any, shall be absolutely due and payable by Licensor to Licensee on July 1, 2007, and Licensor shall make immediate payment of such amount to Licensee without Licensee having to make any further demand or provide any further notice. Licensor will be liable for and shall pay a late charge equal to one and one-half (1.5) times the prime rate in effect as announced by Chase Manhattan Bank, N.A. from time to time on any outstanding balance of the Unpaid Advanced Amount remaining after July 1, 2007, until the entire Advanced Amount has been repaid in full to Licensee. The Parties agree that

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as of the Amendment Date, Licensor shall execute a promissory note, the form of which is attached as Exhibit 3.7.4 (the "Note"), in the amount of the Unpaid Advanced Amount as of the Amendment Date (and as may be reduced pursuant to the terms of this Agreement and the terms of the attached Note).

3.8 Royalty Calculation. In addition to any other rights provided at law or equity, if the Advanced Amount has not been fully repaid by Licensor to Licensee as required hereunder, the amount of any royalties that might otherwise be due and owing from Licensee to Licensor under this Agreement shall in all instances be the amount determined in accordance with the other Sections of this Article 3, less the amount of Unpaid Advanced Amount at the time of such determination.

### ARTICLE 4. LICENSE AND MAINTENANCE FEES.

4.1 License and Maintenance Fees. Licensee shall pay one-time license and maintenance fees ("Milestone Payments") for the achievement of certain goals set forth in Exhibit 4.1 to Licensor within ten (10) business days after each of the events specified in Exhibit 4.1.

ARTICLE 5. DEVELOPMENT OF LICENSED PRODUCTS

5.1 Joint Diligence Obligation. Licensor and Licensee shall both use reasonable commercial efforts to comply with all diligence obligations under the UKRF Licenses to the extent required by the UKRF Licenses.

5.2 Licensee's General Diligence Obligations. Licensee shall use commercially reasonable efforts to Develop and Commercialize First Generation Exclusive Licensed Products.

5.3 (a) Licensee's Specific Diligence Obligations - Uveitis. Licensee agrees to the following specific obligations:

- (i) Licensee shall file an NDA with respect to a First Generation Exclusive Licensed Product for Uveitis by the later of (a) [\*] or (b) [\*] then within a commercially reasonable time after [\*] has been identified and found to be acceptable to the FDA, provided that Licensee has diligently pursued [\*].
- (ii) Licensee shall make the first commercial sale of a First Generation Exclusive Licensed Product for Uveitis in the United States within six (6) months after approval of an NDA for such First Generation Exclusive Licensed Product.

(b) Licensee's Specific Diligence Obligations - Other First Generation Exclusive Licensed Product. In the event Licensee has failed to meet its diligence obligations with respect to First Generation Exclusive Licensed Product for Uveitis pursuant to Section 5.3(a) above, then Licensee agrees to the specific obligations with respect to at least one First Generation Exclusive Licensed Product for an indication other than Uveitis as set forth in Exhibit 5.3.

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5.4 Licensee's Specific Diligence Obligations - Non-Exclusive Licensed Products. In addition to the general obligations set forth in Section 5.2, Licensee further agrees to the specific obligations with respect to Non-Exclusive Licensed Products set forth in Exhibit 5.4.

5.5 Failure to Comply with Diligence Obligations.

(a) If Licensee fails to meet its obligations under Article 5 with respect to a First Generation Exclusive Licensed Product for Uveitis, and does not cure such breach within 90 days after written notice from Licensor, Licensee shall lose its exclusive rights with respect to First Generation Exclusive Licensed Products for Uveitis. In addition, if Licensee fails to meet the specific obligations as set forth in Section 5.3(b) for a First Generation Exclusive Licensed Product for an indication other than Uveitis, and does not cure such breach within 90 days after written notice from Licensor, Licensee shall lose its exclusive rights with respect to First Generation Exclusive Products.

(b) If Licensee fails to meet its obligations under Article 5 with respect to any Non-Exclusive Licensed Product and does not cure such breach within 90 days after written notice from Licensor, Licensee shall lose its rights with respect to the applicable Non-Exclusive Licensed Product. For example, if the diligence obligations as set forth in Exhibit 5.4 have not been met with respect to a Non-Exclusive Licensed Product that (a) has [\*] as an active ingredient; (b) is [\*]; (c) is [\*]; (d) has a [\*] delivery system; (e) is located [\*]; and (f) is for [\*] indications, then Licensee would lose its rights with respect to such Non-Exclusive Licensed Product ("Product A"). As a further example, if the diligence obligations for the above Product A have been met, but any diligence obligation has not been met with respect to a Non-Exclusive Licensed Product that (a) has [\*] as an active ingredient; (b) is [\*]; (c) is [\*]; (d) has a [\*]; (e) is located [\*]; and (f) is for [\*] indications rather than [\*] indications ("Product B"), then Licensee would not lose rights to Product A, but would lose rights to Product B.

(c) The parties agree that Licensee's failure to meet its diligence obligations under Article 5 shall not constitute a basis for termination of this Agreement under Section 11.3.2.

ARTICLE 6. MARKETING OBLIGATIONS. During the term of this Agreement, Licensee and its Affiliates shall use commercially reasonable efforts, consistent with the efforts expended by Licensee with respect to its own proprietary ophthalmic products to:

- Market, sell, distribute, and support the First Generation Exclusive Licensed Product - Uveitis, including, without limitation, establishing, directly or through Sublicensees, an adequate sales force in each Target Market;
- (ii) Obtain third party reimbursement for such Licensed Product, where applicable;
- (iii) Maintain and provide Licensor with such sales and other information customarily maintained by Licensee for purposes of monitoring sales progress on a country by country basis;

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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- (iv) Keep Licensor promptly and fully informed of developments in the markets where such Licensed Product is being sold; and
- (v) Comply with export laws and restrictions and regulations of the Department of Commerce or other United States or foreign agency or authority.

Nothing contained in this Article 6 shall limit any other obligations Licensee may have under this Agreement.

ARTICLE 7. REPORTING AND ACCOUNTING PROVISIONS:

7.1 Royalty Report. Licensee shall make written royalty reports ("Royalty Reports") to Licensor within thirty (30) days after the end of each fiscal quarter of Licensee during the term of this Agreement, stating in each such report the number, description, and aggregate Net Sales of each Licensed Product sold during the preceding three (3) fiscal months of Licensee and upon which a royalty is payable as provided in Article 3 (on a Licensed Product-by-Licensed Product basis; provided, however, that solely with respect to any report with respect to Net Sales made pursuant to Sections 1.28(a) and (b) herein, such thirty (30) day period may be extended to such longer period as Licensee may reasonably require, not to exceed ninety (90) days, to determine the amount of such Net Sales for such fiscal quarter. The first such report shall include all such Licensed Products so sold prior to the date of such report. The first such report shall include all such Licensed Products so sold prior to the date of such report, provided that with respect to Vitrasert Licensed Product, the first such report after the Amendment Date shall reflect only the preceding fiscal months since the last such report for Vitrasert Licensed Product.

7.2 Record Keeping by Licensee. Licensee shall keep records showing the sales of Licensed Products and Third Party Licensed Products in sufficient detail to enable the royalties payable hereunder to be determined. Licensee shall permit its books and records to be examined at Licensor's expense by an independent auditor chosen by Licensor and reasonably acceptable to Licensee during regular business hours and upon reasonable advance notice, but not later than two years following the rendering of any written report and no more often than once per calendar year. Such audit shall be permitted only to the extent necessary to verify the reports provided for in this Article 7. The auditor shall report to Licensor only the amount of royalty payable for the period under audit and shall keep confidential any information learned or obtained during the examination. If the audit shows an underpayment of more than the greater of (i) \$50,000, or (ii) five percent (5%) of the amount otherwise due, Licensee shall reimburse Licensor for the reasonable costs of the audit. Licensee shall promptly remit any underpayment to Licensor. If the audit shows an overpayment, Licensor shall promptly pay such overpayment amount to Licensee upon request, or, at Licensee's election, Licensee may offset such amount against the next payment of royalties or other amounts due Licensor hereunder.

7.3 Termination Report. Licensee also shall make a written report to Licensor within thirty (30) days after the date of any termination of this Agreement providing to Licensor the same information described in Section 7.1 with respect to any Net Sales which were not previously reported to Licensor.

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### ARTICLE 8. OWNERSHIP:

8.1 Ownership. Except as expressly provided otherwise in this Agreement, ownership of Inventions will be determined in accordance with United States patent law and related principles.

8.2 Inventorship. Inventorship of all Inventions (including, without limitation, Improvements) made during the term of this Agreement will be determined in accordance with United States patent law and related principles.

#### 8.3 Licensee Improvements.

(a) Licensee Improvements. If Licensee files any patent application ("Licensee Improvement Application") for any Improvement created, invented or discovered before [\*] ("Licensee Improvement"), Licensee agrees to grant, and hereby grants, to Licensor a non-exclusive, worldwide right and license, with the right to sublicense, under Licensee's interest in such Licensee Improvement Applications, and in any issued patents claiming priority thereto ("Licensee Improvement Patent") or any patent applications claiming priority thereto, to make, have made, use, sell, offer to sell, and import. For the sake of clarity, a Licensee Improvement shall be any Improvement of a product, if the product with respect to which the Improvement was made was a Licensed Product at the time such Improvement was made. Licensee shall promptly notify Licensor of the filing of such Licensee Improvement Application. Notwithstanding the foregoing, in the event of (i) any transfer by Licensee of substantially all of the assets or stock of Licensee's proprietary (branded and/or generic) ophthalmic pharmaceutical business; or (ii) any transfer by Licensor of substantially all of the assets or stock of Licensor's ophthalmics business, "Licensee Improvement" shall only include Improvements created, invented or discovered before the earlier of (x) the effective date of such transfer or (y) [\*].

(b) Royalties. Upon issuance of a Licensee Improvement Patent, and for so long as the making, using, selling, offering to sell, or importing of the Licensee Improvement covered by such Licensee Improvement Patent does not infringe a Valid Claim of a Licensed Patent, Licensor Improvement Patent or other Patent Rights of Licensor, Licensor will owe a royalty to Licensee equal to the lesser of: (i) [\*] of net sales of products the making, using, selling, offering for sale or importing of which would infringe an Issued Patent Claim of a Licensee Improvement Patent ("Licensor Improvement Product"), or (ii) [\*] of all running royalties received by Licensor based on net sales of Licensor Improvement Product by licensees or sublicensees of Licensor. For the avoidance of doubt, if the making, using, selling, offering to sell, or importing of such Licensee Improvement infringes a Valid Claim of a Licensed Patent, Licensor Improvement Patent or other Patent Rights of Licensor, then Licensor will not owe a royalty to Licensee.

(c) Net Sales. For the purposes of this Section 8.3, net sales means, in any case where a Licensor Improvement Product is sold or commercially disposed of for value by Licensor or any sublicensee of Licensor in an arm's length transaction with a third party (other than an Affiliate of Licensor or sublicensee of Licensor), the gross invoice price for such Licensor Improvement Product, less the following: (i) discounts, chargebacks, Medicare or other

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government rebates, and rebates to purchasers actually taken or allowed; (ii) credits or allowances given or made for rejections or return of any previously sold products actually taken or allowed; (iii) to the extent included in such gross invoice price any tax or government charge imposed on the production, import, export, sale, delivery or use of such products, including, without limitation, any value added or similar tax or government charge, but not including any tax levied with respect to income; and (iv) to the extent included in such gross invoice price any reasonable and documented packaging and distribution charges. Net sales shall also include and be deemed to have been made with respect to (A) any Licensor Improvement Product not sold or otherwise transferred to any third party but rather used by Licensor to provide a commercial service and (B) any other transfer of a Licensor Improvement Product for less than arm's length value other than intercompany transfers where the transferee is not the end user. The amount of any net sale as defined in the preceding sentence shall be imputed using the price or prices at which the Licensor Improvement Product at issue is then being sold in transactions covered by the first sentence of this Section or, if no such transactions have occurred, on a reasonable basis to be determined at the time by the Parties. Notwithstanding any other provision of this Section, net sales shall not include the transfer without consideration of any Licensor Improvement Product by Licensor (x) for use in any clinical trial or in any preclinical or other research, (y) as detailing samples or other use to promote additional net sales in amounts consistent with the normal business practices of Licensor, or (z) for compassionate use.

(d) Offsets. If (a) any Licensor Improvement Product is covered by an issued patent or other intellectual property right held by one or more third parties and it becomes necessary for Licensor to obtain a license from such third party or parties under such patent, and/or other intellectual property right and accordingly to pay royalties to such third party(ies) with respect to any net sale or transfer of any Licensor Improvement Product or (b) the therapeutic effect of any Licensor Improvement Product is derived in part from any proprietary product, compound, method or process in-licensed or acquired by Licensor from an unaffiliated third party on an arm's length basis (a "Third Party Licensor Improvement Product"), then Licensor may reduce any royalty otherwise due Licensee by [\*] of the amount of royalty due to such third party, but in no event to less than [\*] of the royalty or other payment which may then be due to Licensee. In addition, if Licensor is required to pay any an upfront or similar fee to any third party(ies), Licensee shall share in the payment of any such consideration which involves more than a running royalty as follows. If, for example, Licensor is required to pay an upfront fee of \$1 Million to a third party, the total consideration then due under Section 8.3 to Licensee shall be reduced by [\*] until [\*] of the upfront fee [\*] has been recouped by Licensor.

(e) Royalties Payable Only Once. Licensor's obligation to pay royalties under this Section 8.3 shall be imposed only once with respect to any net sale of any Licensor Improvement Product. Only a single royalty shall be due and payable by Licensor under this section 8.3 with respect to a Licensor Improvement Product regardless of whether the Licensor Improvement Product is covered by more than one claim of a Licensee Improvement Patent.

(f) Timing of Royalty Payments. Within thirty (30) days after the end of each fiscal quarter of Licensor, Licensor shall pay to Licensee the royalty payment due for each such quarter in U.S. dollars, provided, however, that solely with respect to any royalty payment due with respect to net sales made pursuant to Sections 8.3(c) (A) or (B) herein, such thirty (30) day period

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may be extended to such longer period as Licensor may reasonably require, not to exceed ninety (90) days, to determine the amount of such net sales for such fiscal quarter. If consideration received by Licensor, or a sublicensee of Licensor, pursuant to Section 8.3(c) is in a currency other than U.S. Dollars, the consideration shall be converted from the currency of the country in which the sales were made into U.S. Dollars at the month-end exchange rate for such currency for such sales made during such month as determined by Licensor in accordance with its standard accounting policies and procedures consistently applied during each of Licensor's fiscal quarters. If any royalty or other amount due Licensee is in a non-U.S. Dollar currency, and Licensor is prohibited from exporting that currency from that jurisdiction, Licensor shall pay an amount equal to the royalty or other amount due in such blocked currency into a bank account of Licensee's choice in such jurisdiction, and such deposit shall be deemed to be full satisfaction of Licensor's obligation to make the applicable payment to Licensee.

(g) Withholding Taxes. Licensee and Licensor shall use all commercially reasonable and legal efforts to reduce tax withholding on any payments to be made to Licensee pursuant to Section 8.3. If Licensor concludes that, notwithstanding such efforts, tax withholding under the laws of any country is required with respect to any royalty payment to be made to Licensee under this Agreement, Licensor shall pay any applicable withholding taxes imposed by any such political jurisdiction on such royalty payments, and the amount of any such payments shall be credited against Licensee with, or promptly cause Licensee to be provided with, original receipts or other evidence sufficient to allow Licensee to obtain the benefits of any such tax withholding.

(h) Expiration of Royalty Obligations. Subject to the next sentence, with respect to Licensor Improvement Product, Licensor's obligation to pay a running royalty shall terminate on a Licensor Improvement Product -by- Licensor Improvement Product and country-by-country basis, upon the date that the last to expire of any issued and enforceable Licensee Improvement Patent which covers the manufacture, use, sale, or importing of such Licensor Improvement Product. At the end of each such term, and on a country by country basis, Licensor shall have a non-exclusive, worldwide, irrevocable, fully paid up license to make, have made, use, offer to sell, sell, have sold (including through distributors), and import such Licensor Improvement Product in such country. Notwithstanding any other provision of this Agreement, the provisions of this Section 8.3 shall survive any termination of this Agreement, except in the event Licensee terminates this Agreement pursuant to Section 11.4.2 for Licensor's breach of Section 8.3.

### ARTICLE 9. FILING AND MAINTENANCE OF PATENTS:

Licensor shall in good faith file, prosecute, and maintain all Licensed Patents in the Licensed Territory at its sole discretion and expense (except for Co-Owned Patents for so long as Licensee has exclusive rights to First Generation Exclusive Licensed Products), and except as follows. With respect to Licensed Patents which include claims that cover First Generation Exclusive Licensed Products, for so long as Licensee has exclusive rights to any First Generation Exclusive Licensed Product, Licensor shall keep Licensee informed with respect to the course and conduct of patent applications and prosecution matters. With respect only to Licensed Patents which include claims that cover First Generation Exclusive Licensed Products, Licensor shall use best efforts to incorporate claims and arguments suggested by Licensee, provided said arguments would not materially limit Licensor's ability to prosecute or enforce claims directed to products

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and methods outside the definition of First Generation Exclusive Licensed Products. Licensee represents, warrants and covenants that it will not make suggestions for claims and arguments that, in good faith, Licensee knows or should know would limit the scope of Licensed Patents so as to not cover (directly or under the Doctrine of Equivalents) any product or method of use of a product marketed or to be marketed by Licensee. Licensor shall prosecute and maintain Licensed Patents in the [\*]. At

Licensee's expense, Licensor will prosecute and maintain Licensed Patents in [\*] and any other countries as

Licensee may request. Notwithstanding the foregoing in this Article 9, Licensee shall have the sole right to file, prosecute, and maintain the Co-Owned Patents for so long as Licensee has exclusive rights to First Generation Exclusive Licensed Products, provided that Licensee shall keep Licensor informed with respect to the course and conduct of patent applications and prosecution matters.

ARTICLE 10. ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS:

10.1 Notice to Licensor. Licensee shall inform Licensor promptly in writing of any activity by a third party (an "Infringer"), if Licensee believes such activity might constitute infringement of any Licensed Patent in the Licensed Field, including details then known to Licensee, and provided that Licensee's failure to provide notice under this Section 10.1 shall not impact Licensee's rights under Section 10.6.

10.2 Right to Bring Suit - Licensor; Settlement. With respect only to suits brought against Infringers by Licensor with respect to infringing products that fall within the definition of First Generation Exclusive Licensed Products for which Licensee has exclusive rights under this Agreement, Licensor shall consult with and keep Licensee informed of the progress of such proceedings, including, without limitation, furnishing copies of communications, pleadings and other documents and keeping Licensee informed of settlement efforts and developments, and Licensee shall be entitled to participate with counsel in such proceedings, but at its own expense. With respect only to suits brought against Infringers by Licensor with respect to infringing products that fall within the definition of First Generation Exclusive Licensed Products for which Licensee has exclusive rights under this Agreement, no settlement, consent, judgment, or other voluntary final disposition of a suit with respect to infringement of any Licensed Patent may be entered into without the consent of Licensee, which consent may only be withheld based on Licensee's reasonable business judgment. Notwithstanding the foregoing, Licensor shall not have the right to bring suit under any Co-Owned Patents for so long as Licensee has exclusive rights to First Generation Exclusive Licensed Products.

10.3 Right to Bring Suit - Licensee. With respect only to Licensed Patents (except for Co-Owned Patents for so long as Licensee has exclusive rights to First Generation Exclusive Licensed Products) and with respect to infringing products that fall within the definition of First Generation Exclusive Licensed Product for which Licensee has exclusive rights under this Agreement, if Licensor has not taken legal action or been successful in obtaining cessation of the infringement within (a) ninety (90) days from the date of notice by Licensee; (b) thirty (30) days after Licensee notifies Licensor that Licensee would like to move for injunctive relief; or (c) ten (10) days before the expiration of a period of time set by applicable law in which action must be taken with respect to the alleged infringement (e.g., as may be required under the Hatch-Waxman Act and 35 USC Section 271),

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Licensee has the right but not the obligation to bring suit against an Infringer at Licensee's own expense. This right of Licensee to bring suit, as well as to continue an existing suit, is also conditioned on all of the following requirements:

- (i) If Licensee owns (or has licensed from a third party and has the right to enforce) any patent(s) that literally reads-on the allegedly infringing device or method (collectively, the "Accused Device") practiced by the Infringer, Licensee will include in the complaint one or more claims alleging infringement of all such other patent(s);
- (ii) Licensee has provided evidence to Licensor that there is a good faith basis to believe that the Accused Device is being prepared for commercialization;
- (iii) Licensee will use reasonable efforts to keep Licensor reasonably and timely informed of the pre-litigation and litigation issues and strategy (including, without limitation, furnishing copies of communications, pleading, and other documents and keeping Licensor informed of settlement efforts and developments), and will use reasonable effort to obtain suggestions and strategy from Licensor, including during pre-trial motions and discovery;
- (iv) In the instance of litigation issues and strategies pertaining to defenses or setting strategy for the scope of claims, Licensee shall incorporate all suggestions and strategy from Licensor as may be deemed appropriate in the reasonable business judgment of Licensor; and

Except for joining the legal actions described in this Section 10.3 as a party at Licensee's request, Licensor shall have no obligation regarding such actions unless required to participate by law or contract, but Licensor will provide reasonable assistance at the request of Licensee as provided in Section 10.5 below. However, Licensor shall have the right to participate in any such actions through its own counsel and at its expense.

No settlement, consent judgment or other voluntary disposition of a suit (collectively, "Settlements") with respect to infringement of any Licensed Patent (except for Co-Owned Patents for so long as Licensee has exclusive rights to First Generation Exclusive Licensed Products) may be entered into without the consent of Licensor, which shall not be unreasonably withheld or delayed, and provided that no such consent shall be required where the impact of the settlement, consent judgment or other voluntary disposition is limited to the Licensed Field for First Generation Exclusive Licensed Product for which Licensee has exclusive rights under this Agreement.

10.4 UKRF. If neither Party commences actions or proceedings against Infringers or unauthorized users of any Licensed Patent or Know-how that has been licensed from UKRF within the time periods specified above, UKRF shall, at its expense, have the right to initiate and pursue such action and receive all resulting benefits.

10.5 Expense. If either Party shall initiate or carry on legal proceedings against any Infringer as contemplated hereby, the other Party shall fully cooperate with and supply all assistance

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reasonably required by the first Party. The first Party shall consult with and keep the other Party informed of the progress of such proceedings, including, without limitation, furnishing copies of communications, pleadings and other documents and keeping the other Party informed of settlement efforts and developments, and the other Party shall be entitled to participate with counsel in such proceedings, but at its own expense.

If Licensee initiates and carries on such proceedings, it may offset [\*], including reasonable legal expenses, incurred in regard thereto against any payments owed to Licensor under Article 3 of this Agreement, provided, however, that after the initiation of any such proceedings, no such payment shall be reduced by more than [\*].

Any award paid by any third party as a result of such proceedings (whether by way of settlement or otherwise) shall be first applied to reimbursement of the unreimbursed legal fees and expenses incurred by the Parties, pro rata in proportion to such fees and expenses, then to the payment to Licensor of any amounts that were offset against royalty or other payments as provided above, and then the remainder shall be divided by the Parties pro rata in proportion to the fees and expenses incurred by the Parties, after reimbursement by Licensor of Licensee's expenses pursuant to the royalty off-set set forth above, in connection with any action against the Infringer; provided, however, that each Party (regardless of the extent, if any, to which such Party participates in such action) shall be entitled, after reimbursement of any applicable expenses and royalties as provided herein, to no less than [\*] of any net recovery.

10.6 Co-Owned Patents. Notwithstanding anything to the contrary in this Section 10.6, Licensee has the sole right, at Licensee's own expense, to bring and control any suits under the Co-Owned Patents against a third party for so long as Licensee has exclusive rights to First Generation Exclusive Licensed Products. Licensor shall have the right to participate in any such suits through its own counsel and at its expense. Licensor shall reasonably assist Licensee, with respect to such suits, at Licensee's request and expense. If required by law, Licensee may join Licensor as a party to any such suit, provided that Licensee shall hold Licensor harmless from, and indemnify Licensor against, any costs, expenses, or liability that Licensor incurs in connection with such suit. To the extent a suit is related to Co-Owned Patents and not any Licensed Patents, Licensor Improvement Patents or Other Technology, Licensee shall have the right to settle any such suit for so long as Licensee has exclusive rights to First Generation Exclusive Licensed Products. Any award paid by any third party as a result of such proceedings (whether by way of settlement or otherwise) (a) shall be first applied to reimbursement of the unreimbursed legal fees and expenses incurred by either Party pro rata in proportion to such fees and expenses, then (b) Licensor shall receive an amount equal to such reasonable approximation of the royalties that Licensee would have paid to Licensor if Licensee had sold the infringing products and services rather than the infringer. Any remaining amounts after reimbursement pursuant to (a) and (b) above shall be solely for the account of Licensee for proceedings under this Section 10.6.

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11.1 Expiration of Royalty Obligations. Subject to the next sentence, with respect to Non-Exclusive Licensed Products, Licensee's obligation to pay a running royalty shall terminate on a Licensed Product-by-Licensed Product and country-by-country basis, upon the date that the last to expire of any issued and enforceable Licensed Patent or Licensor Improvement Patent which covers the manufacture, use, sale, or importing of such Non-Exclusive Licensed Product in such country expires. At the end of each such term, and on a country by country basis, Licensee shall have a non-exclusive, worldwide, irrevocable, fully paid up license to make, have made, use, offer to sell, sell, have sold (including through distributors), and import such Licensed Products in such country. Subject to the next sentence, with respect to First Generation Exclusive Licensed Products, Licensee's obligation to pay a running royalty shall terminate on a Licensed Product-by-Licensed Product and country-by-country basis, upon the date that is the later of (i) the last to expire of any issued and enforceable Licensed Patent or Licensor Improvement Patent which covers the actual manufacture, use, sale, or importing of such Licensed Product in such country, or (ii) ten (10) years from the last new FDA or other comparable approval with respect to an indication for the applicable Licensed Product in the applicable country but in no event more than twenty (20) years from the date of the first FDA or comparable approval for the first indication with respect to such Licensed Product in such country. At the end of each such term, and on a country by country basis, Licensee shall have an irrevocable, fully paid up license under the Licensed Patents in the Licensed Field to make, have made, use, offer to sell, sell, and import such Licensed Product in such country.

11.2 Term. This Agreement shall continue for the Term, unless earlier terminated by Licensor or Licensee as provided herein.

11.3 Termination by Licensor. Licensor shall have the right to terminate this Agreement and the licenses granted hereunder upon the happening of any of the following events:

11.3.1 Failure to Pay. Licensee fails to pay or cause to be paid any royalty or other payment which has become due to Licensor under this Agreement, within thirty (30) days after receiving a written request from Licensor to make such payment or to cause such payment to be made; provided, however, that if any payment is disputed in good faith by Licensee, Licensee may delay paying the disputed portion of such payment by invoking the dispute resolution procedure set forth in Article 22. If the dispute resolution procedure results in a final determination that Licensee owes some or all of such disputed amount, Licensee shall pay such owed amount within thirty (30) days of the determination pursuant to Article 22 as provided therein, together with interest thereon from the date such amount was due at one and one-half (1.5) times the prime rate in effect at such determination as announced by Chase Manhattan Bank, N.A. In addition to any other termination rights Licensor may have under this Section, if Licensee fails to pay Licensor such owed amount within thirty (30) days of the final determination as set forth above, Licensor may, subject to the next sentence, terminate this Agreement upon thirty (30) days' written notice to Licensee. Notwithstanding the foregoing, if Licensee's failure to pay or cause to be paid royalties or other payments is limited to royalties or payments for: (a) a First Generation Exclusive Licensed Product, then Licensor's right to terminate pursuant to the provisions of this Section 11.3.1 shall be limited to termination

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of Licensee's rights to all First Generation Exclusive Licensed Product; (b) a Non-Exclusive Licensed Product, then Licensor's right to terminate pursuant to the provisions of this Section 11.3.1 shall be limited to termination of Licensee's rights to all Non-Exclusive Licensed Product; and (c) a Vitrasert Licensed Product, then Licensor's right to terminate pursuant to the provisions of this Section 11.3.1 shall be limited to termination of Licensee's rights to all Vitrasert Licensed Product;

- 11.3.2 Breach. Licensee has materially breached or materially defaulted under this Agreement as a result of a breach or default of any other provision of this Agreement and has not cured such breach or default within ninety (90) days after written notice from Licensor to Licensee specifying the nature of such breach or default in reasonable detail; provided, however, that if Licensee has invoked the dispute resolution procedure set forth in Article 22, this Agreement may not be terminated except in accordance with such Article; and further provided that if Licensee's material breach or default is limited to a material breach or default relating to: (a) First Generation Exclusive Licensed Product, then Licensor's right to terminate pursuant to the provisions of this Section 11.3.2 shall be limited to termination of (i) the specific First Generation Exclusive Licensed Product for which the breach or default occurred; or (ii) with respect to any further material breach or default thereafter, Licensee's rights to all First Generation Exclusive Licensed Product; (b) Non-Exclusive Licensed Product, then Licensor's right to terminate pursuant to the provisions of this Section 11.3.2 shall be limited to termination of (i) the specific Non- Exclusive Licensed Product for which the breach or default occurred; or (ii) with respect to any further material breach or default thereafter, Licensee's rights to all Non-Exclusive Licensed Product; and (c) Vitrasert Licensed Product, then Licensor's right to terminate pursuant to the provisions of this Section 11.3.2 shall be limited to termination of Licensee's rights to all Vitrasert Licensed Product; or
- 11.3.3 Bankruptcy. The filing of a bankruptcy petition by or against the Licensee, the entry by Licensee into a trust deed, creditor's arrangement or comparable proceeding, or the appointment of a receiver for substantially all of the assets or business of Licensee that is not dismissed within ninety (90) days from the date of such filing or appointment.

11.4 Termination by Licensee. Licensee shall have the right to terminate this Agreement and the licenses granted hereunder upon the happening of any of the following events:

11.4.1 Without Cause. Licensee may terminate this Agreement at any time without cause in its entirety or with respect to a Vitrasert Licensed Product or a Non-Exclusive Licensed Product on ninety (90) days' written notice to Licensor. Upon termination of this Agreement in its entirety, Licensee shall remain liable for all Milestone Payments, royalty payments, and other payments under this Agreement falling due before the end of the first ninety (90) days after Licensor's receipt of the notice of termination without cause. Thereafter, for an additional ninety (90) days (for a total of one hundred eighty (180) days after Licensor's receipt of the notice of the notice of termination), Licensee shall continue to be liable for all payments, including, but not limited to, royalty payments, due under the Agreement, excluding Milestone Payments. Upon termination of this Agreement with respect to a Vitrasert Licensed Product or a Non-Exclusive Licensed Product, Licensee shall remain liable for all payments then due with respect to such Licensed

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Product(s), and thereafter Licensee shall have the right for one hundred eighty (180) days to sell off any inventory of such Licensed Product(s), and shall remain liable for the royalties due, if any, with respect to such sales.

11.4.2 Breach. Licensee may terminate this Agreement if Licensor has materially breached or defaulted under any provision of this Agreement and has not cured such breach or default within ninety (90) days after written notice from Licensee to Licensor specifying the nature of such breach or default in reasonable detail; provided, however, that if Licensor has invoked the dispute resolution procedure set forth in Article 22, this Agreement may not be terminated except in accordance with such Article.

11.5 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Section 365(n) of Title 11 of the United States Code ("Title 11"), licenses of rights to "intellectual property" as defined in Title 11. During the term of this Agreement each Party shall create and maintain current copies to the extent practicable of all such intellectual property. If a bankruptcy proceeding is commenced by or against one Party under Title 11, the other Party shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of such other Party, shall be promptly delivered to it (a) upon such Party's written request following the commencement of such bankruptcy proceeding, unless the Party subject to such bankruptcy proceeding, or its trustee or receiver, elects within thirty (30) days to continue to perform all of its obligations under this Agreement, or (b) if not delivered as provided under clause (a) above, upon such other Party's request following the rejection of this Agreement by or on behalf of the Party subject to such bankruptcy proceeding. If Licensee has taken possession of all applicable embodiments of the intellectual property of Licensor pursuant to this Section 10.5 and the trustee in bankruptcy of Licensor does not reject this Agreement, Licensee shall return such embodiments upon request. If Licensor seeks or involuntarily is placed under Title 11 and the trustee rejects this Agreement as contemplated under 11 U.S.C. 365(n)(1), Licensee hereby elects, pursuant to Section 365(n) to retain all rights granted to Licensee under this Agreement to the extent permitted by law.

11.6 Effect of Termination. Upon termination of this Agreement for any reason, nothing herein shall be construed to release either Party from any obligation that matured prior to the effective date of such termination. The provisions of the following Sections shall survive termination of this Agreement for any reason: Article 1, Sections 2.4, 2.7, 2.8 (except as set forth therein), 2.9, 2.10, 3.5, 3.7, 7.2, 7.3, 8.1, 8.2, 8.3 (except where termination of this Agreement is pursuant to Section 11.4.2 for Licensor's breach of Sections 8.3), Sections 11.1, 11.3, 11.4, 11.5, 11.6, 11.7, Articles 12, 14, 15, 16, 17, 21, 22, 23, 24, 25, 26, 27, 28, 30, 31, 32, 34, 35 and 36. Licensee and any Sublicensee may, after a termination and complete and sell Licensed Products which Licensee can clearly demonstrate were in the process of manufacture at the time of such termination, provided that Licensee shall pay to Licensor any royalties or other payments due on the sale of such Licensed Products and shall submit reports, in accordance with this Agreement.

11.7 Grant Back. Except under the circumstances described in the last sentence of this Section, solely for the purpose of enabling Licensor and its licensees to continue the

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development and commercialization of First Generation Exclusive Licensed Products to which Licensee no longer has rights, Licensee shall grant to Licensor a fully paid-up, irrevocable, non-exclusive, worldwide license, with the right to grant sublicenses under the Licensee Patents (as defined below), if any, to make, have made, use, sell, and import any First Generation Exclusive Licensed Product that is at the time being commercialized (other than a Third Party Licensed Product) and for no other purpose. For purposes of the foregoing, "Licensee Patent" means any Patent Right existing at the time of termination of this Agreement which would block Licensor from practicing any Patent Right included in the Licensed Patents. Licensor shall not be entitled to any grant back under this Section if this Agreement is terminated by Licensee under Section 11.4.2 or 11.5 or if Licensee's obligation to pay royalties has expired pursuant to Section 11.1.

### ARTICLE 12. OWNERSHIP OF CLINICAL IP:

12.1 Clinical IP Outside Licensees License Rights. Subject to any rights or restrictions imposed by applicable third parties, and to protections for Confidential Information herein, Licensee shall provide Licensor with a Right of Access to Clinical IP, provided that Licensor shall not use such Clinical IP for a Licensed Product in the Licensed Field so long as Licensee has a license for such Licensed Product under this Agreement.

12.2 Clinical IP-Cooperation. Licensee shall use commercially reasonable efforts, and shall reasonably cooperate with Licensor, to provide Licensor with such waivers, irrevocable cross reference letters, assignments, and/or other reasonable documentation as may be necessary or useful for Licensor's full exercise of any Right of Access to Clinical IP granted by Licensee to Licensor pursuant to this Article 12.

### ARTICLE 13. UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION LICENSES:

Licensor shall maintain the UKRF Licenses in full force and effect, including (without limitation) making all royalty payments. Licensor shall not, after the Amendment Date, amend or modify the UKRF Licenses without Licensee's prior written consent, which consent shall not be unreasonably withheld or delayed, provided, however, that after providing prior written notice to Licensee, Licensor may amend or modify the UKRF Licenses without Licensee's prior written consent so long as such amendment would not have an adverse impact on Licensee's rights or increase the cost to Licensee of exercising such rights. Notwithstanding the foregoing, if UKRF delivers a notice of nonpayment of royalties or of any other breach of any of the UKRF Licenses to Licensor, Licensor shall immediately notify Licensee and Licensee shall have the right to make such payments directly to UKRF or otherwise to cure such breach. In addition, Licensor shall inform UKRF of the existence of this Agreement and request UKRF to send a copy of all default notices to Licensee simultaneously with any notice of default to Licensor and to permit Licensee to assume, upon receipt of written notice from Licensee to UKRF, Licensor's obligations under the UKRF License(s) to which such default notice applies. Licensee shall have the right to offset the payments made to UKRF and the cost of curing any default under any of the UKRF Licenses against future royalties or other payments due Licensor under this Agreement as provided in Article 19.

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### ARTICLE 14. INDEMNIFICATION:

14.1 Indemnification of Licensee. Subject to Sections 14.2 and 14.3, Licensor shall indemnify, defend and hold Licensee and each of its officers, directors, employees, agents and consultants (each a "Licensee Indemnitee") harmless from and against all third party costs, claims, suits, expenses (including reasonable attorneys' fees and expenses, whether incurred as a result of a third party claim or a claim to enforce this provision), damages, and, solely with respect to the Vitrasert Licensed Product, any amounts paid by Licensee to a third party pursuant to any agreement between Licensee and the third party for the manufacture, distribution, promotion, or sale of the Vitrasert Licensed Product (a "Vitrasert Third Party Loss") (collectively, including a Vitrasert Third Party Loss, "Losses") to the extent arising out of or resulting from (i) any material breach or failure by Licensor in the performance or non-performance of its obligations or covenants under this Agreement; (ii) any breach by Licensor of any representation or warranty hereunder; (iii) the manufacture, marketing, possession, use, sale or other disposition by Licensor or any of its sublicensees other than Licensee or any Sublicensee of any Licensed Product (except to the extent where such Losses arise or result from any negligence of Licensee (or any contract manufacturer of Licensee) in the manufacture of any such Licensed Product or the failure of Licensee (or any contract manufacturer of Licensee) to manufacture such Licensed Product in accordance with GMPs); (iv) FDA enforcement actions, inspections, product recalls or market withdrawals relating to a Licensed Product to the extent arising out of or resulting from Licensor's marketing, possession, use, sale or other disposition of the Licensed Product; and (v) any material breach or failure by Licensor in the performance of any Clinical Agreement or Trial Agreement except for (a) the payment obligations expressly assumed by Licensee pursuant to Article 36, and (b) breaches of a Clinical Agreement or Trial Agreement to the extent resulting from a delay by Licensee in providing notice of termination or assignment and assumption to third parties pursuant to Article 36. Notwithstanding the foregoing or anything else in the Agreement to the contrary, Licensee's remedies under this Section 14.1 or any other provision of this Agreement, including without limitation Section 2.11, for any Vitrasert Third Party Loss and for Frustration Claims pursuant to Section 2.11 herein, shall be limited to, in the aggregate, and satisfied solely out of, the amount of royalties for Vitrasert Licensed Products received by Licensor after the date of Licensor's receipt of written notice from Licensee of such Frustration Claim or Vitrasert Third Party Loss specifying the nature and amount of the claim or loss in reasonable detail.

14.2 Indemnification of Licensor. Subject to Sections 14.1 and 14.2, Licensee shall indemnify, defend and hold Licensor and each of its officers, directors, employees, agents and consultants (each a "Licensor Indemnitee") harmless from and against all Losses to the extent arising out of or resulting from (i) any material breach or failure by Licensee in the performance or non-performance of its obligations or covenants under this Agreement; (ii) any breach by Licensee of any representation or warranty hereunder; (iii) the manufacture, marketing, possession, use, sale or other disposition of any Licensed Product by Licensee or any Sublicensee (except to the extent where such Losses arise or result from any negligence of Licensor (or any contract manufacturer of Licensor) in the manufacture of any such Licensed Product or the failure of Licensor (or any contract manufacturer of Licensor) to manufacture the Licensed Product in accordance with GMPs); and (iv) FDA enforcement actions, inspections, product recalls or market withdrawals relating to a Licensed Product to the extent

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arising out of or resulting from Licensee's marketing, possession, use, sale or other disposition of the Licensed Product or the failure of Licensee (or any contract manufacturer of Licensee) to manufacture the Licensed Product in accordance with GMPs or the specifications for the Licensed Product.

14.3 Limitation of Liability. Except where a Party commits a willful, intentional breach of any material provision of this Agreement, no breaching Party shall be responsible or liable under any provision of this Agreement or under any contract, theory of negligence or strict liability, or under any other legal or equitable theory for any resulting indirect, special, incidental, consequential, punitive, or exemplary damages of the other Party, including (without limitation) damages such as lost revenues or profits and damage to goodwill or reputation. Nothing in this Section shall relieve any Party of any obligation with respect to any third party claim.

14.4 Procedure for Indemnification. If an event occurs which a Party believes requires indemnification (Indemnification Event"), the Party seeking indemnification ("Indemnified Party") shall give prompt written notice to the other Party ("Indemnifying Party") providing reasonable details of the nature of the event and the basis of the indemnity claim. The Indemnifying Party shall then have the right, at its expense and with counsel of its choice, to defend, contest, or otherwise protect against any such action. The Indemnified Party shall also have the right, but not the obligation, to participate at its own expense in the defense with counsel of its choice. The Indemnified Party shall cooperate as requested by the Indemnifying Party to assist it in defending or contesting any such action. If the Indemnified Party fails to promptly notify the Indemnified Party of the occurrence of an Indemnification Event, to the extent, but only to the extent, that such failure results in a material adverse effect on the Indemnifying Party, the Indemnified Party shall not be entitled to indemnification with respect to such Indemnification Event. If the Indemnifying Party fails within thirty (30) days after receipt of such notice: (a) to notify the Indemnified Party of its intent to defend, or (b) to defend, contest, or otherwise protect against such suit, action, investigation, claim or proceeding, or fails to diligently continue to provide such defense after undertaking to do so, the Indemnified Party shall have the right, upon ten (10) days' prior written notice to the Indemnifying Party, to defend, settle and satisfy any such suit, action, claim, investigation or proceeding and recover the costs of the same from the Indemnifying Party.

14.5 Insurance. To the extent required by the UKRF Licenses, Licensee will maintain product liability insurance, with an endorsement naming UKRF, the University of Kentucky, its Board of Trustees, agents, officers, and employees as additional insureds covering liabilities for the production, manufacture and/or sale of the Licensed Product by Licensee or any Sublicensee. The policy of insurance shall contain a provision of non-cancellation except upon the provision of thirty (30) days' notice to the University of Kentucky. Policy limits shall be not less than \$1,000,000 per occurrence.

# ARTICLE 15. TRADEMARKS:

Licensee shall own the logos, trade names, copyrights, trademarks, and other commercial symbols ("Marks") developed or used in connection with any and all Licensed Products. During and after the term of this Agreement, Licensor shall not directly or indirectly contest the

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ownership, validity or originality of the Marks for the Licensed Products, the Third Party Licensed Products, and the goodwill represented by any of the foregoing Marks. Licensor will not use any name or other symbol confusingly similar to or, in the reasonable judgment of Licensee, suggestive of any of the foregoing Marks. If Licensor learns of any unauthorized use of any such Marks it shall promptly inform Licensee in writing.

ARTICLE 16. REPRESENTATIONS AND WARRANTIES:

16.1 Representations and Warranties of Both Parties. As of the Amendment Date, each Party hereby represents and warrants to the other Party that:

- It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its incorporation.
- (ii) It has all requisite corporate power and authority and is free to enter into this Agreement and to perform its obligations hereunder without the need for any other action or consent;
- (iii) It has taken all corporate and other action to authorize the execution and delivery of this Agreement, any other documents executed and delivered in connection herewith and the performance of its obligations hereunder and thereunder, all of which shall be valid, binding and enforceable in accordance with its or their terms;
- (iv) The execution, delivery, and performance of this Agreement (a) will not violate or require it to obtain any consent or approval, to make any filing or to provide any notice, or (b) will not conflict with or result in a breach of any agreement or other instrument to which it is a party or by which it is bound;
- (v) It is not a party to any agreement with any third party which is in conflict with the rights granted to the other pursuant to this Agreement, including, without limitation, with respect to the Licensed Patents; and
- (vi) Except as described in Exhibit 16.1(vi), there is no litigation, proceeding, or governmental investigation to which it is a party pending or threatened against it, or, to its knowledge, against any third party, as to which there is a likelihood of an outcome(s) that would, individually or in the aggregate, reasonably be expected to delay or otherwise materially impair its ability to perform its obligations contemplated by this Agreement.

16.2 Representations and Warranties of Licensor. Licensor hereby represents and warrants to Licensee as of the Amendment Date that:

(i) The UKRF Licenses set forth in Exhibit 1.47 are the only UKRF Licenses, all of which are in full force and effect and have not been amended or modified without Licensee's written consent; Licensor has complied with all provisions of the UKRF Licenses; Licensor owes no royalty or other payment to UKRF or any affiliate of UKRF under the UKRF Licenses and there does not exist any event of

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default with respect to Licensor under any of the UKRF Licenses which, after notice or lapse of time or both, would constitute an event of default with respect to Licensor;

- (ii) Licensor has all rights and consents necessary to grant the rights and licenses granted to Licensee under this Agreement;
- (iii) Except for the Co-Owned Patents, and as described in Exhibit 16.2(iii), Licensor warrants that it owns the entire right, title, interest in and to the Licensed Patents and that the entire interest is not encumbered in any manner;
- (iv) Licensor has made written request of all patent counsel engaged by Licensor for all opinions of counsel, clearances, studies, licenses, and agreements relating to Licensed Products, and has provided Licensee with all information relating to Licensed Products received by Licensor as of the Amendment Date in response to such requests and further, has provided Licensor all other formal written opinions of counsel, licenses, and agreements relating to First Generation Exclusive Licensed Products;
- (v) The Persons who are listed on Exhibit 16.2(v) are all of the officers, employees, and consultants of Licensor as of the Amendment Date. Except as set forth in Exhibit 16.2(v), each of such Persons has signed a confidentiality and invention disclosure and assignment agreement (a) which requires such individual to observe confidentiality restrictions at least as strict as those between the Parties, and (b) which results in Licensor having unrestricted ownership of any intellectual property created by such individual during his or her employment or engagement by Licensor, including (without limitation) all intellectual property created or developed by such individual before the date of this Agreement during such employment or engagement; and
- (vi) Licensor has not received any written communication from a third party that a Licensed Product may or actually does infringe or otherwise violate any intellectual property right of such third party. Licensor's officers as of the Amendment Date have not received any oral communication from a third party that a Licensed Product may or actually does infringe or otherwise violate any intellectual property right of such third party.

As used in this Agreement, (i) "to Licensor's knowledge" (or any equivalent term) means to the best actual knowledge, as of the date of this Agreement, of Licensor and its officers after diligent investigation, without commissioning special searches or studies, and (ii) "to Licensee's knowledge" (or any equivalent term) means to the best actual knowledge, as of the date of this Agreement, of Licensee and its officers after diligent investigation, without commissioning special searches or studies.

ARTICLE 17. WARRANTY DISCLAIMER:

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES, AND HEREBY DISCLAIMS, ANY EXPRESS OR IMPLIED WARRANTY INCLUDING, WITHOUT LIMITATION, ANY IMPLIED

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WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT WITH RESPECT TO ANY OF THE RIGHTS OR INTERESTS GRANTED HEREUNDER, INCLUDING WITHOUT LIMITATION THOSE WITH RESPECT TO THE LICENSED PATENTS OR LICENSOR IMPROVEMENT PATENTS OR KNOW-HOW OR ANY LICENSED PRODUCT.

ARTICLE 18. OPERATIONS IN COMPLIANCE WITH LAW:

Up to the date of this Agreement, each Party has complied, and in exercising the rights granted to each Party by this Agreement, each Party shall comply, in all material respects with all applicable laws, including, without limitation, the requirements of 35 U.S.C. Section 200 et seq. and all regulations promulgated thereunder, as amended, and any similar or successor statutory regulations (collectively, the "Federal Patent Policy"). To the extent that any Licensed Patent or Licensor Improvement Patent claims an invention subject to Federal Patent Policy, the license granted to Licensee hereunder with respect to such Licensed Patent or Licensor Improvement Patent may be subject to any royalty-free, non-exclusive license granted to the United States Government pursuant to 35 U.S.C. Section 204(c) (4).

ARTICLE 19. INFRINGEMENT OF THIRD PARTY'S PATENTS:

Licensee shall promptly send Licensor a copy of any notice or communication from a third party alleging that Licensee's exercise of its rights under this Agreement infringe or otherwise violate such third party's intellectual property rights ("Notice"). Licensor shall have the first right, but shall not be obligated, to respond to the Notice. If Licensor does not elect to respond, Licensor shall promptly inform Licensee and Licensee may respond to the Notice. If Licensee defends such proceedings, it may offset [\*], including reasonable legal expenses, incurred in regard thereto against any payments owed to Licensor under Article 3, provided, however, that no such payment shall be reduced by more than [\*] by any such offset [\*]. Licensee shall continue to perform its reporting obligations under Article 7 and otherwise continue to perform its obligations hereunder.

Licensee shall not settle any infringement, misappropriation, or other claim subject to this Article 19 without the consent of Licensor.

If any Licensed Product is covered by an issued patent or other intellectual property right held by one or more third parties and it becomes necessary for Licensee to obtain a license from such third party or parties under such patent, and/or other intellectual property right and accordingly to pay royalties to such third party(ies) with respect to any Net Sale of any Licensed Product, then Licensee may reduce any royalty otherwise due Licensor by [\*] of the amount of royalty payment due to such third party, but in no event to less than [\*] of the royalty which may then be due to Licensor. In addition, if Licensee is required to pay any an upfront or similar fee to any third party(ies), Licensor shall share in the payment of any such consideration which involves more than a running royalty as follows. If, for example, Licensee is required to pay an upfront fee of \$1 Million to a third party, the royalty payments then due Licensor shall be reduced by [\*] until [\*] of the upfront fee [\*] has been recouped by Licensee.

 $[\,\star\,]$  - INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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If Licensee is required to pay any damages (i.e., something other than prospective royalties and upfront or similar fees ) to the third party, Licensee shall be responsible for the payment of any such damages to the third party and shall be permitted to recoup one-half (1/2) of such payment from Licensor as follows: If, for example, Licensee is required to pay damages of \$1 Million to the third party, Licensor's royalty payments otherwise due under this Agreement shall be reduced by [\*] until [\*] of the damages [\*] have been recouped by Licensee.

Except as set forth below, any reduction of royalties due to Licensor as a result of a recoupment of running royalties, upfront fees, and damages in the aggregate arising out of a third party claim of infringement or violation of intellectual property rights under this Section shall not reduce any single royalty payment otherwise due Licensor hereunder by more than [\*].

Licensor shall provide Licensee with a copy of any notice of default or breach received by Licensor which relates in any way to the UKRF Rights within five (5) business days of receipt of such notice. If Licensor fails to make any payment before any applicable cure period has expired, Licensee may make such payment in Licensor's name and on Licensor's behalf before such cure period expires, and Licensee may fully recover any payment made by Licensee under this paragraph at the applicable rate described in the next paragraph. Licensor's remedy for recovering payments made by Licensee to any third party pursuant to this paragraph shall be limited to recovery from such third party and not Licensee.

Except as set forth below, where Licensee seeks recoupment for payment(s) made to UKRF as a result of Licensor's failure to make any payment to UKRF, Licensee shall be permitted to recoup [\*] of such payment to UKRF against [\*] percent of the royalty then due to Licensor as follows ("[\*] Recoupment Rate"): Licensee may reduce any royalty payment otherwise due to Licensor hereunder by [\*] of such royalty payment less any royalties payable by Licensor to UKRF ("Net Royalty Amount"). [\*]. The [\*] Recoupment Rate shall not apply where Licensee seeks recoupment for payment(s) made to UKRF where Licensor's decision not to make any payment to UKRF (i) was made on the basis of a written opinion of reputable outside patent counsel; (ii) the opinion and any other relevant information was fully disclosed to Licensee within a reasonable time prior to Licensor's decision not to pay; and (iii) where, following such disclosure, Licensee failed to require Licensor to make the payment in accordance with the provisions of the previous paragraph on the basis of the written opinion of counsel as provided therein. In such case Licensee shall be permitted to recoup [\*] of Licensee's payment to UKRF by reducing any royalty payment otherwise due to Licensor hereunder by [\*].

 $[\star]$  - INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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### ARTICLE 20. FORCE MAJEURE:

Neither Party shall be liable for any failure to perform arising out of causes beyond the control and without the fault or negligence of such Party. Such causes include, but are not limited to, acts of God; acts of the public enemy; acts of terrorism, natural disasters such as fire or flood or unusually severe weather; quarantine restrictions; strikes; and freight embargoes.

### ARTICLE 21. CHOICE OF LAW/FORUM:

Any legal or other action hereunder shall be brought in the State and federal courts nearest the principal place of business of the defendant in any such action, and this Agreement shall be construed and interpreted and its performance shall be governed by the substantive laws of the State where such courts are located, i.e., New York, if Licensee is the defendant, and Massachusetts, if Licensor is the defendant, without regard to the state's conflict of laws principles. The Parties consent to the exclusive personal jurisdiction and venue of such courts in the event of such action. In construing this Agreement, neither Party shall have been deemed to have drafted this Agreement, and no court or arbitrator will construe or interpret this Agreement in favor of a Party based on the presumption that it did not draft the term or clause at issue, it being agreed that each Party has ably represented itself and has been ably represented by counsel.

## ARTICLE 22. DISPUTE RESOLUTION:

If there is any dispute arising out of or relating to this Agreement or a Party's performance or failure to perform hereunder, such dispute shall, at the written request of either Party be submitted to the top executive officer of each Party, or another executive officer of a Party designated by the top executive officer as his or her representative for such purpose. The initial Representatives are the General Manager, North American Pharmaceuticals, for Licensee, and the President of Licensor. The Representatives shall meet as soon as reasonably practicable to consider the matter and each shall each use reasonable commercial efforts to effect a resolution. If the Representatives are able to resolve the dispute, the resolution shall be set forth in a written instrument signed by each of them.

If the Representatives are not able to resolve the dispute within thirty (30) days of their first meeting or within such extended period they agree upon, they shall proceed to non-binding arbitration by a skilled mediator familiar with the commercial and manufacturing processes of the pharmaceutical industry and pursuant to the rules of an organization specializing in alternatives to disputes, such as the CPR Institute for Dispute Resolution, End Dispute, or the AAA. If the Parties cannot agree upon a single mediator within the next 30 days, they shall each select a mediator and the two selected shall select the sole mediator. If a Party does not select a mediator, the mediator shall use his best efforts to make a nonbinding decision on the merits of the case within sixty (60) days, and the Parties shall use their best reasonable commercial efforts to cooperate with the mediator. The mediator need not give reasons for his decision.

If the Parties are not able to resolve their dispute through mediation, such dispute may, if they agree, be submitted to binding arbitration pursuant to the expedited procedures and in accordance

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with the Patent Licensing Rules of the AAA. The arbitrator shall be mutually selected by the Parties or, if they cannot agree, each Party shall designate one arbitrator to represent it in the selection process and the two arbitrators shall appoint a third arbitrator who shall arbitrate such dispute or difference. Such selection process shall be completed within sixty (60) days from the end of the period during which they attempted to resolve the dispute through the mediation process. The disputed matter shall be arbitrated at such location as the Parties shall mutually designate or, if they are not able to agree on such location, at a location selected by the arbitrator. The selected arbitrator shall, if reasonably possible, be one who is familiar with the commercial and manufacturing practices of the pharmaceutical industry.

The arbitrator's award shall be final and binding on the Parties and enforceable by either Party in any court of competent jurisdiction. The fees and expenses of the arbitrator shall be shared equally by the Parties.

#### ARTICLE 23. NOTICES:

Any notice, request, instruction or other communication required or permitted to be given under this Agreement shall be in writing and shall be given by sending such notice properly addressed to the other Party's address shown below (or any other address as either Party may indicate by notice in writing to the other from time to time as required by this Article): (i) by hand or by prepaid registered or certified mail, return receipt requested, (ii) by a nationally recognized overnight courier service, or (iii) via facsimile (provided such facsimile is sent by a machine which acknowledges receipt of the transmission) at the following addresses:

If to Licensor:

Control Delivery Systems 400 Pleasant Street Watertown, MA 02472 Attn: Paul Ashton, Ph.D., President Facsimile Number: 617-926-2313

With a copy to:

Control Delivery Systems 400 Pleasant Street Watertown, MA 02472 Attn: Lori Freedman, General Counsel Facsimile Number: (617) 926-5050

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Place	
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(617)	951-7050
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## If to Licensee:

Bausch & Lomb Incorporated 1400 N. Goodman Street Rochester, NY 14609 Attn: Gary Phillips, M.D. Corporate Vice President, Global Pharmaceutical and Vitreoretinal Facsimile Number: (585) 338-0811

With a copy to:

Bausch & Lomb Pharmaceuticals, Inc. One Bausch & Lomb Place Rochester, NY 14604 Attn: Robert B. Stiles Senior Vice President and General Counsel Facsimile Number: (585) 338-8706

Any notice, if mailed properly addressed, postage prepaid, shall be deemed made (i) three (3) days after the date of mailing as indicated on the certified or registered mail receipt, (ii) on the next business day if sent by overnight courier service, or (iii) on the date of delivery if hand delivered or the date of transmission if sent by facsimile transmission.

# ARTICLE 24. MERGER CLAUSE:

This Agreement contains the entire understanding between the Parties and supersedes all proposals, oral and written, all negotiations, conversations or discussions between or among the Parties relating to the subject matter of this Agreement and restates the 1999 Agreement and the Vitrasert Agreement, both as amended, in their entirety.

ARTICLE 25. INTEGRATION CLAUSE:

No amendment or modification to this Agreement shall be valid or binding upon the Parties unless made in writing and executed by authorized representatives of both Parties.

ARTICLE 26. SEVERABILITY CLAUSE:

Any terms or provision of this Agreement which is found to be invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity of enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

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### ARTICLE 27. NO WAIVER:

The failure of either Party to terminate, seek redress for a breach of, or to insist on strict performance of any term, covenant, condition, or provision contained in this Agreement shall not act as a waiver of rights or of the right to require future compliance and the term, covenant or provision in question shall remain in full force and effect.

ARTICLE 28. TRANSFERABILITY OF RIGHTS AND OBLIGATIONS:

This License and Agreement shall inure to the benefit of and be binding upon the successors, assigns, or other legal representatives of the Parties. Notwithstanding the foregoing, neither Party may assign, delegate, or subcontract its right and obligations hereunder without the prior written consent of the other Party, which shall not be unreasonably withheld, except that (i) no consent to assignment shall be necessary in the case of any transfer by Licensee of substantially all of the assets or stock of Licensee's proprietary (branded and/or generic) ophthalmic pharmaceutical business, (ii) no consent shall be necessary in the case of any Sublicense pursuant to Section 2.1.1, and (iii) no consent to assignment shall be necessary in the case of any transfer by Licensor of substantially all of the assets or stock of Licensor's ophthalmics business. In addition, if Licensor directly or indirectly delegates or transfers any rights or obligations under this Agreement, it shall be a condition of such delegation or transfer that its obligations under Sections 2.3 and 2.4 are expressly assumed by, and become binding upon, such delegatee or transferee.

## ARTICLE 29. PATENT MARKING:

Licensee shall mark all Licensed Products sold or otherwise disposed of by it in the United States under the license granted in this Agreement with the word "Patent" and the number of the Licensed Patent. All License Products shipped of sold in other countries shall be marked in such a manner as to conform with the patent laws and practice of the country to which such products are shipped or in which such products are sold.

ARTICLE 30. INTENTIONALLY OMITTED

### ARTICLE 31. INDEPENDENT CONTRACTORS:

Licensor and Licensee are not partners, joint venturers or agents of one another and shall at all times act as independent contractors without the right or authority to bind each other with respect to any agreement, representation, or warranty made with or to any third party. Except as otherwise stated herein, Licensor and Licensee each shall be responsible for all costs, expenses, and taxes, arising from the conduct of its own business.

# ARTICLE 32. CONFIDENTIALITY:

32.1 Confidentiality. Notwithstanding any other provision herein, during the term of this Agreement and for a period of ten (10) years from termination of this Agreement, each Party ("Receiver") will hold in confidence, will not disclose to others (except those Affiliates, attorneys, accountants, stockholders, investment bankers, advisers or other consultants who are bound by an obligation of confidentiality), and will not use for any purpose not contemplated

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by this Agreement, any technical or business information (including the terms and conditions of this Agreement) Receiver obtains from the other Party ("Discloser") in connection with this Agreement (collectively, the "Confidential Information") provided that the Receiver may disclose Confidential Information: (a) as otherwise expressly provided in this Agreement, (b) as required by applicable law or any listing agreement with, or the rules and regulations of, any applicable securities exchange or the National Association of Securities Dealers, (c) necessary to secure any required consents under this Agreement as to which the other Party has been advised, (d) consented to in writing by the furnishing Party, (e) in confidence, to accountants, banks, and financing sources and their advisers, or (f) in confidence, to the other party (and their Affiliates, attorneys, accountants, stockholders, investment bankers, advisers or other consultants who are bound by an obligation of confidentiality) in a merger, acquisition or license or proposed merger, acquisition or license, or the like, and further provided that with respect to disclosures of the terms and conditions of this Agreement made pursuant to the filing of this Agreement as an exhibit to a document filed with the SEC, the filing Party shall use commercially reasonable efforts to obtain confidential treatment under the Securities Act of 1933 or the Securities Exchange Act of 1934 of those portions of this Agreement identified to the filing Party in writing by the other Party in advance of the filing (the filing party shall provide the other Party with reasonable advance notice of the filing to permit the other Party to make the confidentiality request described above). Except as otherwise set forth above, Receiver shall make Discloser's Confidential Information available to persons within Receiver's organization only on a "need to know" basis, and Receiver shall inform all persons to whom such Confidential Information is made available of the confidential nature of the Confidential Information and the restrictions comprised hereunder and shall require such persons to keep the Confidential Information confidential as provided in this Section. However, this confidentiality obligation shall not extend to any portion of the Confidential Information which: (i) is known to Receiver as documented by its written records at the time of disclosure; or (ii) is or becomes public or generally available to the public through publication or otherwise but through no fault of Receiver; or (iii) corresponds in substance to information furnished to Receiver on a nonconfidential basis by a third party having a bona fide right to do so and not having any confidential obligation, direct or indirect, to Discloser with respect to the same; or (iv) corresponds to information furnished by Discloser to any third party on a nonconfidential basis except in limited consumer testing; or (v) Receiver can demonstrate was developed by Receiver independently of the disclosure of the Confidential Information by Discloser; or (vi) is disclosed by Receiver pursuant to a legal requirement, provided Receiver has complied with the provisions set forth in Section 32.2 below.

32.2 External Disclosure. If Receiver becomes legally required to disclose any of Discloser's Confidential Information, Receiver shall notify Discloser promptly of such requirement so that Discloser may seek a protective order or other appropriate remedy concerning such disclosure. Receiver will consult with Discloser, if requested to do so, regarding the nature and extent of the required disclosure and will cooperate to limit such disclosure to the extent practical. Unless specifically requested otherwise by Control Delivery Systems Inc., Bausch & Lomb Incorporated will direct all communications it receives from potential or existing investors in Control Delivery Systems, Inc. to Steve McCluski (Senior Vice President and Chief Financial Officer), Robert Bailey (Vice President, Assistant General Counsel and Assistant Secretary), or Gary Phillips (Corporate Vice President, Global Pharmaceutical and Vitreoretinal) (or their respective successors).

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### ARTICLE 33. RELINQUISHMENT:

33.1 UKRF Letter Agreement. The Licensee hereby relinquishes, agrees to relinquish and shall not exercise, any and all rights or causes of actions Licensee has, now, in the past, or in the future, pursuant to the Letter Agreement dated June 9, 1999, as between UKRF, Licensor and Licensee (the "UKRF Letter Agreement"). Licensee hereby agrees that the relinquishment of its rights under the UKRF Letter Agreement shall be fully evidenced by this Amendment without the need for further documentation of such relinquishment, and supercedes any prior negotiations, understandings, agreements, instruments and representations with respect to the UKRF Letter Agreement.

33.2 Covenant Not to Compete. The Licensee hereby relinquishes, agrees to relinquish and shall not exercise, any and all rights or causes of actions Licensee has, now, in the past, or in the future, pursuant to the Covenant Not to Compete dated June 9, 1999, as between Licensee and Paul Ashton, Ph.D. (the "Covenant Not to Compete"). Licensee hereby agrees that waiver of its rights under the Covenant Not to Compete shall be fully evidenced by this Amendment, and supersedes any prior negotiations, understandings, agreements, instruments and representations with respect to the Covenant Not to Compete.

### ARTICLE 34. NO LIMIT TO REMEDIES:

Subject to the terms of this Agreement, the existence or choice of any one remedy available to a Party shall not limit or otherwise restrict a Party from choosing any remedy available, it being understood that a Party's remedies are cumulative.

## ARTICLE 35. COUNTERPARTS:

This Agreement may be executed in counterparts, each of which shall be enforceable against the Party actually executing such counterpart, and which together shall constitute one instrument.

### ARTICLE 36. TRANSITION OBLIGATIONS:

36.1 Clinical/Trial Agreements. The Parties wish to reflect the transfer to Licensee of pre-clinical, clinical, manufacturing and regulatory activities which were being performed by Licensor and/or Licensee with respect to current clinical trials relating to DME, Uveitis and ARMD (the "Clinical Activities"). As agreed upon by the Parties, prior to Licensor's withdrawal of its IND covering such Clinical Activities, Licensee has provided: (a) notice of assignment and assumption to third parties under the third party contracts related to the Clinical Activities listed on Exhibit 36.1A (the "Clinical Agreements"); and (b) a notice of termination (as executed by Licensor) to third parties under third party clinical trial agreements listed on Exhibit 36.1B ("Trial Agreements"). Consequently, Licensor hereby transfers and assigns to Licensee, and Licensee hereby assumes, (i) all Clinical Agreements; (ii) all outstanding bills for Clinical Activities provided by Licensor to Licensee as of June 18, 2003; (iii) all payment obligations arising on or after June 18, 2003 under the Clinical Agreements; and (iv) all payments obligations for services required under the Trial Agreements through the date of termination of such Trial Agreements. However, notwithstanding any payments by Licensee with respect to any Clinical or Trial Agreement, Licensor shall be responsible for any material breach or failure by Licensor in the performance of any such agreement prior to the

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assumption by Licensee, or the termination, of such agreement, except for (x) the payment obligations assumed by Licensee pursuant to this Section 36.1; or (y) breaches of a Clinical or Trial Agreement resulting from a delay by Licensee in providing notice of termination or assignment and assumption to third parties pursuant to subsections (a) or (b) above.

36.2 Clinical Activities Data. Up through December 31, 2003 ("Transition Period"), Licensor shall cooperate with Licensee and provide reasonable access to, answer questions regarding, and transfer to Licensee, all relevant information possessed by Licensor regarding the Clinical Activities.

36.3 Transition Space. Licensor shall have the right to control its premises, but Licensor shall provide space at its premises during the Transition Period through November 30, 2003, to permit Licensee and its consultants and representatives ("Licensee Transition Personnel") to transition the Clinical Activities to Licensee. Licensor hereby grants to Licensee a license to permit Licensee Transition Personnel to use and occupy such portions of Licensor's premises as are reasonably designated by Licensor to the extent needed to perform such transition activities on behalf of Licensee. The Licensee Transition Personnel shall have access to all applicable records and information reasonably necessary to complete the transition of the Clinical Activities to Licensee as contemplated in this Article 36. Licensee shall require all Licensee Transition Personnel to (i) observe Licensor's codes of conduct and attire; (ii) observe all building security rules and procedures at Licensor's premises; (iii) return all building passes, security cards or other access materials immediately upon completion and delivery of the transition activities contemplated under this Agreement; (iv) work during Licensor's ordinary business hours, unless otherwise agreed, and follow Licensor's reasonable instructions as to where to work; and (v) adhere to Licensor's reasonable restrictions regarding confidential information they may be exposed to at Licensor's premises. As soon as possible after receipt of Licensor's reasonable request that Licensee remove from Licensor's premises any Licensee Transition Personnel failing to adhere to such restrictions, Licensee will cause such individual to be removed.

36.4 Insurance. In connection with the assumption of the payment obligations pursuant to Section 36.1, Licensor shall promptly provide Licensee with a copy of all insurance policies maintained as of the date hereof in connection with Clinical Activities, including without limitation the Clinical and Trial Agreements. Such insurance shall be in form, substance, and amount reasonably satisfactory to Licensee. Licensor shall maintain such insurance in force for as long as any obligation under any Clinical or Trial Agreement. Licensee shall be named as an additional insured on all such policies, none of which may be cancelled or materially amended without prior notice to, and the written consent of, Licensee, which consent will not be unreasonably withheld. If there is any default under any such policy, Licensee shall have the right, but not the obligation, to cure such default, including paying any premiums thereunder. If Licensee pays any premium or other amount due from Licensor under any such policy or otherwise incurs any out-of-pocket cost in curing any such default, such amount(s) will be deemed part of and added to the Unpaid Advanced Amount under Article 3.

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IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed in duplicate originals by its duly authorized officer or representative.

BAUSCH & LOMB INCORPORATED	CONTROL DELIVERY SYSTEMS, INC.
By: /s/Gary Phillips	By: /s/ Michael J. Soja
Printed Name: Gary Phillips	Printed Name: Michael J. Soja
Title: Corporate Vice President	Title: V. Ex President and CFO

FIGURE 1 [\*] FIGURE 2

[\*]

[\*] - INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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# EXHIBIT 1.23(a) LICENSED PATENTS, PATENT APPLICATIONS AND IDFS

# I. ISSUED PATENTS AND PENDING PATENT APPLICATIONS

[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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[\*] - INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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[\*]

 $[\,\star\,]$ -INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

## EXHIBIT 1.47 UKRF LICENSES

1. License Agreement By and Between University of Kentucky Research Foundation and Controlled Delivery Systems, Inc., dated October 20, 1991, as amended August 10, 1993

-Patent Rights: US Patent No. 5,378,475 "Sustained Release Drug Delivery Devices"

2. License Agreement By and Between University of Kentucky Research Foundation and Controlled Delivery Systems, Inc. dated October 31, 1995

-Patent Rights: USSN 08/187,462 "Co-drugs as a Method of Controlled Delivery" (abandoned)

3. License Agreement By and Between University of Kentucky Research Foundation and Controlled Delivery Systems, Inc. dated September 9, 1997

-Patent Rights: US Patent No. 5,836,935 "Implantable Refillable Controlled release Device to Delivery Drugs Directly into an Internal Portion of the Body"

4. License Agreement By and Between University of Kentucky Research Foundation and Controlled Delivery Systems, Inc. dated September 9, 1997

-Patent Rights: US Patent No. 5,773,019 "Implantable Controlled Release Device to Delivery Drugs to an Internal Portion of the Body"

5. License Agreement By and Between University of Kentucky Research Foundation and Controlled Delivery Systems, Inc. dated September 9, 1997

-Patent Rights: US Patent No. 5,681,964 "Permeable Non-Irritating Prodrugs of non-steroidal, anti-inflammatory agents"

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# EXHIBIT 2.3 PATENTS, PATENT APPLICATIONS, AND INVENTION DISCLOSURE FORMS NOT SUBJECT TO NON-SUIT

[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED. [\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

# EXHIBIT 2.10 LICENSEE COVENANT NOT TO FILE: IDFS

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[\*]
[\*]- Indicates material that has been omitted and for which confidential
treatment has been requested. All such information has been filed with the
Commission pursuant to Rule 24b-2 promulgated under the Securities and Exchange
Act of 1934, as amended.

## OPTION CERTIFICATE

### No. [ ]

[DATE]

BAUSCH & LOMB INCORPORATED, a New York corporation ( "B&L"), for value received and pursuant to Section 3.7.3 of an Amended and Restated License Agreement (the "License Agreement"), dated as of December 9th, 2003, by and between B&L and Control Delivery Systems, Inc., a Delaware corporation ("CDS"), hereby certifies that CDS, or its registered assigns (the "Option Holder"), is entitled to purchase from B&L, in whole or in part, 600,000 shares (the "Option Shares") of CDS common stock, par value \$0.01 per share ("Common Stock"), at the purchase price of \$5.00 per share (the "Exercise Price"), at any time or from time to time prior to 5:00 P.M., New York, New York time, on JUNE 30, 2004 (the "Expiration Time"), all subject to the terms, conditions and adjustments set forth below in this Option Certificate.

- 1. Exercise.
  - a. Notice of Exercise. The Option Holder may exercise this option, from time to time, in whole or in part, by delivering a notice of exercise to B&L in substantially the attached form at any time prior to the Expiration Time.
  - b. Closing of Exercise. The closing of any exercise of this option must occur at the offices of B&L.
    - i. B&L Deliveries. At the closing, B&L shall deliver to the Option Holder:
      - A. certificates representing the Option Shares being purchased endorsed for transfer or accompanied by executed stock powers,
      - B. customary representations regarding ownership of the Option Shares, and
      - C. an agreement to indemnify the Option Holder for any breach of the representations regarding ownership of the Option Shares
    - ii. Option Holder Deliveries. At the closing, the Option Holder shall deliver to B&L the aggregate exercise price for the Option Shares being purchased by wire transfer or check drawn on immediately available funds.

2. Transferability of Option. This option is transferable by the Option Holder in whole or in part. B&L shall maintain a register of the names and addresses of Option Holders and the transferees of this option. Upon the surrender of this Option Certificate and a completed assignment form in substantially the attached form, B&L shall at its expense execute and deliver

to the Option Holder, its transferees, or both a new Option Certificate or Certificates covering the total number of Option Shares covered by the surrendered Option Certificate or Certificates.

- 3. Representations, Warranties and Covenants.
  - a. Representations. B&L represents and warrants to the Option Holder as follows as of the date of this Option Certificate:
    - i. B&L has the full power and authority to grant this option.
    - ii. B&L is the registered holder and beneficial owner of the Option Shares.
    - iii. The Option Shares are unencumbered except for encumbrances imposed by the Stockholders' Agreement (the "Stockholders Agreement"), dated as of August 8, 2000, by and among CDS and the stockholders party thereto, and the Standstill Agreement (the "Standstill Agreement"), entered into in connection with the License Agreement by CDS and B&L.
  - b. No Disposition of Option Shares. Until the Expiration Time, B&L shall not and shall not agree to dispose of any interest in the Option Shares or create or allow to be created any encumbrance on the Option Shares.
  - c. Cooperation. B&L shall cooperate with the Option Holder to effectuate any amendments or waivers to the Stockholders Agreement, the Standstill Agreement or any other similar agreement, or any amendment to CDS' Certificate of Incorporation, to enable the closing of any purchase of Option Shares to occur, provided that B&L shall not be required to incur any costs or expenses other than out of pocket expenses or costs to its own advisors in connection therewith.
- 4. Adjustment to Option Shares.
  - a. Recapitalization. If the outstanding shares of Common Stock are changed into or exchanged for a different number or kind of shares or other CDS securities by reason of any recapitalization, reclassification, stock split, stock dividend, combination, subdivision or similar transaction, the number and kind of Option Shares and the Exercise Price shall be appropriately and proportionally adjusted.
  - b. Sale of CDS. If CDS consolidates or merges with any other entity and the Common Stock is converted into or exchanged for stock or other securities of another entity or for cash or other property (any of the foregoing, "Merger Consideration"), B&L shall retain the Merger Consideration, and the Option Holder shall receive upon exercise the Merger Consideration attributable to the shares of Common Stock being purchased.
- 5. Miscellaneous.
  - Remedies/No Waivers. B&L stipulates that in the event of any default or threatened default by B&L in the performance of this Option Certificate, the Option Holder's remedies at law will be inadequate. A court may specifically enforce the terms of this

Option Certificate or enjoin any violation or impending violation of the terms of this Option Certificate. Any delay or failure to enforce this Option Certificate does not impair the right to enforcement and is not a waiver of any breach or any future breach. All remedies of the Option Holder shall be cumulative and not alternative.

- b. Choice of Law/Forum. Any legal or other action pertaining to the terms of this Certificate must be brought in the state and federal courts nearest the principal place of business of the defendant in the action. This Option Certificate shall be construed and interpreted in accordance with, and its performance shall be governed by, the substantive laws of the state where such courts are located, without regard to the state's conflict of laws principles. B&L and the Option Holder consent to the exclusive personal jurisdiction and venue of such courts in the event of such action.
- c. Notices.
  - i. Delivery. Any notice, request, instruction or other communication required or permitted to be given pursuant to this Option Certificate shall be in writing and shall be given as follows to the address indicated in Section 5(c)(iii):
    - A. by hand,
    - B. by prepaid registered or certified mail, return receipt requested,
    - C. by a nationally recognized overnight courier service, or
    - D. via facsimile.
  - ii. Timing of Effectiveness. Any notice shall be deemed made as of the time set forth in this Section 5(c)(ii).
    - A. If delivered by hand, upon delivery.
    - B. If sent by mail, 3 days after the date of mailing indicated on the certified or registered mail receipt.
    - C. If sent by overnight courier service, on the next business day.
    - D. If sent by facsimile, on the date of confirmed receipt.
  - iii. Addresses for Notice. The addresses for notice are as
    follows:
    - A. If to the original Option Holder

Control Delivery Systems 400 Pleasant Street Watertown, MA 02472 Attn: Paul Ashton, Ph.D., President Facsimile Number: 617-926-2313

Control Delivery Systems 400 Pleasant Street Watertown, MA 02472 Attn: Lori Freedman, General Counsel Facsimile Number: (617) 926-5050

and to:

with a copy to:

Ropes & Gray One International Place Boston, MA 02110 Attn: Mary E. Weber Facsimile Number: (617) 951-7050.

- B. If to a subsequent Option Holder, to the address showing on the transfer register maintained by B&L for such Option Holder.
- C. If to B&L:

Bausch & Lomb Incorporated
1400 N. Goodman Street
Rochester, NY 14609
Attn: Gary Phillips, M.D.
Corporate Vice President, Global Pharmaceutical
and Vitreoretinal
Facsimile Number: (585) 338-0811

with a copy to:

Bausch & Lomb Pharmaceuticals, Inc. One Bausch & Lomb Place Rochester, NY 14604 Attn: Robert B. Stiles Senior Vice President and General Counsel Facsimile Number: (585) 338-8706

- d. Amendments and Waivers. This Option Certificate may be amended only by a written instrument signed by B&L and the Option Holder. B&L shall record any amendments of this Option Certificate in the register maintained to record transfers. Any term of this Option Certificate may be waived only by a written instrument signed by the waiving party.
- e. Severability. Any terms or provision of this Option Certificate which are invalid or unenforceable in any jurisdiction are ineffective only to the extent of such invalidity or unenforceability and only in such jurisdiction. The invalidity of any term of this Option Certificate in one jurisdiction does not impair the enforceability of the

remaining terms or affect the validity of the term in any other jurisdiction.

f. Construction. The headings contained in this Option Certificate are for convenience only and are not a part of this Option Certificate.

IN WITNESS WHEREOF, this Option Certificate has been duly executed by B&L and as of the date first written above.

BAUSCH & LOMB INCORPORATED

By:		 
Name:		
Title:		

[SIGNATURE PAGE TO B&L OPTION CERTIFICATE]

## FORM OF NOTICE OF EXERCISE

# [To be executed and delivered only upon exercise of option]

To:Bausch & Lomb Incorporated

The undersigned registered holder of an option to purchase Control Delivery Systems, Inc. common stock, par value \$.01 per share, from Bausch & Lomb Incorporated hereby exercises such Option for [\_\_\_\_\_] shares. The closing of this exercise shall occur on [\_\_\_\_].(1) At the closing, the undersigned requests that B&L transfer the shares being purchased to [\_\_\_\_], whose address is [\_\_\_\_].

Dated: [\_\_\_\_]

# Signature(2)

- -----

- (1) This date must be a business day on or before the 30th day following the date of the notice of exercise.
- (2) The signature must conform to the name of the holder as specified on the face of the Option Certificate or to a registered assign on the transfer register maintained by B&L. Otherwise, the person or entity must provide B&L with evidence of valid assignment.

[FORM OF EXERCISE FOR B&L OPTION CERTIFICATE]

## FORM OF ASSIGNMENT

[To be executed and delivered to Bausch & Lomb only upon assignment of option, in whole or in part]

For value received, the undersigned registered holder of an option to purchase Control Delivery Systems, Inc. common stock, par value \$.01 per share, from Bausch & Lomb Incorporated hereby sells, assigns and transfers unto [\_\_\_\_\_\_], whose address is [\_\_\_\_\_], the rights represented by such option to purchase [\_\_\_\_\_] (3) shares of Control Delivery Systems, Inc. common stock and appoints [\_\_\_\_\_] attorney to make such transfer on the transfer register maintained by Bausch & Lomb Incorporated for such purposes, with full power of substitution in the premises.

Dated: [\_\_\_\_]

Signature(4)

- -----

- (3) Insert the number of shares assigned. In the case of a partial assignment, Bausch & Lomb Incorporated will execute and deliver a new Option Certificate representing the unassigned portion of the option to the assigning holder.
- (4) The signature must conform to the name of the holder as specified on the face of the Option Certificate or to a registered assign on the transfer register maintained by B&L. Otherwise, the person or entity must provide B&L with evidence of valid assignment.

## EXHIBIT 3.7.4 FORM OF PROMISSORY NOTE

THIS NOTE HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR APPLICABLE STATE SECURITIES LAWS AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR SUCH LAWS COVERING THE TRANSFER OR AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE BORROWER THAT SUCH REGISTRATION IS NOT REQUIRED.

### PROMISSORY NOTE

## \$6,794,719.00

December 9th, 2003

FOR VALUE RECEIVED, the undersigned Control Delivery Systems, Inc. (the "Borrower") promises to pay to Bausch & Lomb Incorporated (the "Lender") on the Maturity Date (as hereinafter defined), the principal sum of Six Million Seven Hundred Ninety-Four Thousand Seven Hundred and Nineteen Dollars (\$6,794,719), or such lesser principal amount as may be outstanding hereunder. Payments hereunder shall be made to the Lender at 1400 N. Goodman Street, Rochester, New York or at such other address as the Lender may specify.

1. MATURITY DATE. The term "Maturity Date" means July 1, 2007. If the Borrower has not repaid the entire principal amount due to the Lender under this Note by the Maturity Date (whether by prepayment or by offset as described below), the Borrower will be liable for and shall pay a late charge at an annual rate of one and one-half (1.5) times the prime rate in effect as announced by the JPMorgan Chase Bank, N.A. from time to time, on any outstanding balance of the principal amount remaining after the Maturity Date. This late charge will compound annually and will accrue commencing on the day following the Maturity Date until the entire remaining principal amount of this Note has been repaid.

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2. OFFSET. The Borrower agrees that the Lender will have the right to offset and apply certain amounts owing by the Lender to the Borrower under the Amended and Restated License Agreement dated as of December 9th, 2003 between the Borrower and the Lender (the "License Agreement") against the amount of principal due under this Note. Such amounts that may be offset include (a) any Milestone Payments (as defined in the License Agreement) owing from Lender to Borrower, and (b) any royalty payments otherwise due Borrower under Article 3 of the License Agreement, in each case until the entire remaining principal amount of this Note has been fully repaid. If the Lender elects to apply any amounts described in the preceding sentence against principal due hereunder, the Lender shall provide an executed Certificate of Offset of Principal in the form of Exhibit A to the Borrower promptly after each such application; provided, however, that if such application is with respect to royalty payments owed by the Lender to the Borrower, Lender shall furnish the Certificate of Offset of Principal to the Borrower in conjunction with the Royalty Report referenced in Section 7.1 of the License Agreement. The remaining principal amount owed under this Note shall be reduced to the amount indicated on such Certificate. Notwithstanding the foregoing, neither the existence of this Note nor the provision of one or more Certificates of Offset of Principal by the Lender shall affect any of the Borrower's rights under the License Agreement, including without limitation the Borrower's right to audit and dispute the amounts of any royalty payments pursuant to Sections 7.1 and 7.2 of the License Agreement.

3. PREPAYMENTS. This Note may be prepaid in whole or from time to time in part without premium or penalty, including without limitation by means of any payment made by the Borrower under Section 3.7.3 of the License Agreement.

4. UNSECURED. The indebtedness represented by this Note is unsecured.

5. DEFAULT.

5.1  $\,$  Each of the following shall constitute an "Event of Default" for purposes of this Note:

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5.1.1 the Borrower fails to pay any amount on this Note when it is due and payable;

5.1.2 there occurs any material event of default by the Borrower under the License Agreement, and any applicable grace period shall have expired;

5.1.3 if the Borrower files a petition in bankruptcy or is adjudicated bankrupt, or if a petition in bankruptcy is filed against the Borrower and such petition is not discharged or dismissed within sixty (60) days thereafter, or if the Borrower makes any assignment for the benefit of its creditors or any arrangement pursuant to any bankruptcy law, or if a trustee, custodian or receiver is appointed for the Borrower or any of its assets or property;

5.1.4 there occurs any material event of default by Borrower under any agreement relating to its Material Financing Debt. "Material Financing Debt" means any financing debt (other than under this Note) outstanding in an aggregate amount of principal (whether or not due) and accrued interest exceeding \$5,000,000; or

5.1.5 the dissolution or liquidation of Borrower.

5.2 If there shall occur an Event of Default under subparagraphs 5.1.1, 5.1.2 or 5.1.4 above, Lender shall be entitled by notice to Borrower to declare this Note and any interest accrued hereon and all liabilities of Borrower hereunder to be forthwith due and payable; and if there shall occur an Event of Default under subparagraphs 5.1.3 or 5.1.5 above, then this Note and any interest accrued hereon and all liabilities of Borrower hereunder to Lender shall automatically become forthwith due and payable; and in each case the same shall thereupon become due and payable without presentment, demand, protest or notice of any kind, all of which are hereby expressly waived.

5.3 Borrower agrees to pay all reasonable costs and expenses incurred by Lender (including reasonable attorney's fees), if any, in connection with the enforcement or collection of this Note arising after the occurrence of any Event of Default or any event which with notice or lapse of time or both would constitute an Event of Default, unless such occurrence is cured by Borrower within any applicable grace period or such reimbursement is not required

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by the terms of any waiver granted by Lender in respect of such occurrence. The obligations of Borrower under this paragraph shall survive the payment of this Note.

6. WAIVERS. The Borrower waives to the extent not prohibited by applicable law (a) all presentments, demands for performance, notices of nonperformance (except to the extent required by the provisions hereof), protests, notices of protest and notices of dishonor, (b) any requirement of diligence or promptness on the part of the Lender in the enforcement of its rights under this Note, (c) all notices of every kind which may be required to be given by any statute or rule of law, (d) any valuation, stay, appraisement or redemption laws and (e) any defense of any kind (other than payment) which the Borrower may now or hereafter have with respect to its liability under this Note. No failure or delay on the part of Lender in the exercise of any power or right in this Note shall operate as a waiver thereof, and no exercise or waiver of any single power or right, or the partial exercise thereof, shall affect the Lender's rights with respect to any and all other rights and powers.

7. ASSIGNABILITY. This Note shall bind and inure to the benefit of the Borrower and the Lender and their permitted successors and assigns. Notwithstanding the foregoing, neither party may assign, delegate, or subcontract its rights and obligations hereunder without the prior written consent of the other party, which shall not be unreasonably withheld or delayed, except that (i) no consent to assignment shall be necessary in the case of any transfer by the Lender of substantially all of the assets or stock of Lender's proprietary (branded and/or generic) ophthalmic pharmaceutical business, and (ii) no consent to assignment shall be necessary in the case of any transfer by the Borrower of substantially all of the assets or stock of the Borrower's opthalmics business, and provided that such assignee, delegatee or transferee shall be at least as creditworthy as the Borrower (where creditworthiness of the assignee, delegatee or transferee shall take into account the fair value of the opthalmics business being transferred to such assignee, delegatee or transferee)

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8. LOSS OR MUTILATION OF NOTE. Upon receipt by the Borrower of evidence satisfactory to the Borrower of the loss, theft, destruction or mutilation of this Note, together with indemnity reasonably satisfactory to the Borrower, in the case of loss, theft or destruction, or the surrender and cancellation of the Note, in the case of mutilation, the Borrower shall execute and deliver to Lender a new Note of like tenor as this Note.

9. NOTICES. Any notice, request, instruction or other communication required or permitted to be given under this Note shall be in writing and shall be given by sending such notice properly addressed to the other party's address shown below (or any other address as either party may indicate by notice in writing to the other from time to time as required by this paragraph): (i) by hand or by prepaid registered or certified mail, return receipt requested, (ii) by a nationally recognized overnight courier service, or (iii) via facsimile (provided such facsimile is sent by a machine which acknowledges receipt of the transmission) at the following addresses:

If to the Borrower:

Control Delivery Systems 400 Pleasant Street Watertown, MA 02472 Attn: Chief Executive Officer Facsimile Number: 617-926-2313

With a copy to:

Control Delivery Systems 400 Pleasant Street Watertown, MA 02472 Attn: Lori Freedman, General Counsel Facsimile Number: (617) 926-5050

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and to:

Ropes & Gray One International Place Boston, MA 02110 Attn: Mary E. Weber Facsimile Number: (617) 951-7050

If to the Lender:

Bausch & Lomb Incorporated 1400 N. Goodman Street Rochester, NY 14609 Attn: Gary Phillips, M.D. Corporate Vice President, Global Pharmaceutical and Vitreoretinal Facsimile Number: (585) 338-0811

With a copy to:

Bausch & Lomb Pharmaceuticals, Inc. One Bausch & Lomb Place Rochester, NY 14604 Attn: Robert B. Stiles Senior Vice President and General Counsel Facsimile Number: (585) 338-8706

Any notice, if mailed properly addressed, postage prepaid, shall be deemed made (i) three (3) days after the date of mailing as indicated on the certified or registered mail receipt, (ii) on the next business day if sent by overnight courier service, or (iii) on the date of delivery if hand delivered or the date of transmission if sent by facsimile transmission.

10. GOVERNING LAW; CONSENT TO JURISDICTION. This Note shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed entirely within such State, including all matters of construction, validity and performance (including Section 5-1401 and 5-1402 of the New York General Obligations Law but excluding all other choice of law and conflicts of law rules). Any legal or other action hereunder shall be brought in the State and federal courts nearest the

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principal place of business of the defendant in any such action, and the parties consent to the exclusive personal jurisdiction and venue of such courts in the event of such action.

11. CONSTRUCTION. In construing this Note, neither party shall have been deemed to have drafted this Note, and no court or arbitrator will construe or interpret this Note in favor of a party based on the presumption that it did not draft the term or clause at issue, it being agreed that each party has ably represented itself and has been ably represented by counsel.

12. WAIVER AND AMENDMENT. Any term of this Note may only be amended, waived or modified with the written consent of the Borrower and the Lender of this Note.

[The remainder of this page is intentionally left blank.]

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IN WITNESS WHEREOF, the undersigned has caused this Note to be executed as of the date first above written.

#### BORROWER

CONTROL DELIVERY SYSTEMS, INC.

Ву:	 	 	
Name:	 	 	

LENDER

BAUSCH & LOMB INCORPORATED

Ву:\_\_\_\_\_

Title:\_\_\_\_\_

Name:\_\_\_\_\_

Title:\_\_\_\_\_

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	Amount of	Unpaid	
	Principal	Principal	Notation
Date	Repaid/Offset	Balance	Made By

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#### CERTIFICATE OF OFFSET OF PRINCIPAL

Reference is hereby made to the Promissory Note dated December 9th, 2003 by Control Delivery Systems, Inc. in favor of Bausch & Lomb Incorporated in the original principal amount of \$6,794,719 (the "Note"). Capitalized terms not defined herein have the meanings given such terms in the Note.

In accordance with paragraph 2 of the Note, the Lender hereby certifies to the Borrower that the Lender has elected to offset against the remaining principal amount of the Note the following funds owed by the Lender to the Borrower under the License Agreement:

	Description of	Amount	Remaining Principal Balance
Date of Offset	Amounts Offset	Offset	of Note (after Offset)

IN WITNESS WHEREOF, the undersigned has caused this Certificate to be executed as of the date first above written.

LENDER

BAUSCH & LOMB INCORPORATED

By:

Name:\_\_\_\_\_

Title:

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#### EXHIBIT 4.1 MILESTONE PAYMENTS

Licensee shall make the following one-time Milestone Payments to Licensor within ten (10) business days after each of the following events:

(i) [\*] - the later of (a) June 1, 2000, or (b) the date Phase III clinicals for uveitis have begun for the first Licensed Product;

(ii) [\*] - the later of (a) March 1, 2001, or (b) the date Phase III clinicals for the first Licensed Product for DME or ARMD have begun;

(iii) [\*] - the later of (a) September 1, 2002, or (b) the date an NDA has been filed for the first Licensed Product for uveitis;

(iv) [\*] - the later of (a) March 1, 2003, or (b) the date an NDA has been filed for the first First Generation Exclusive Licensed Product for either DME or ARMD;

(v) [\*] - the later of (a) November 1, 2003, or (b) the date the FDA has approved the NDA for the first First Generation Exclusive Licensed Product for a uveitis related indication; and

(vi) [\*] - the later of (a) April 1, 2004, or (b) the date the FDA has approved the NDA for the first First Generation Exclusive Licensed Product for either a DME or ARMD related indication.

 $[\,\star\,]-\text{INDICATES}$  MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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# EXHIBIT 5.3

# LICENSEE'S SPECIFIC DILIGENCE OBLIGATIONS - FIRST GENERATION EXCLUSIVE LICENSED PRODUCT (NON-UVEITIS INDICATIONS)

[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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LICENSEE'S SPECIFIC DILIGENCE OBLIGATIONS - NON-EXCLUSIVE LICENSED PRODUCTS

[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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# EXHIBIT 16.1(vi) LITIGATION, PROCEEDINGS, GOVERNMENTAL INVESTIGATIONS

Not Applicable

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### EXHIBIT 16.2(iii) EXCEPTIONS TO OWNERSHIP OF LICENSED PATENTS

1. US Patent No. 5,378,475 "Sustained Release Drug Delivery Devices"

Owned by University of Kentucky Research Foundation and licensed to Control Delivery Systems, Inc. pursuant to the License Agreement By and Between University of Kentucky Research Foundation and Control Delivery Systems, Inc., dated October 20, 1991, as amended August 10, 1993

2. USSN 08/187,462 "Co-drugs as a Method of Controlled Delivery" (abandoned)

Owned by University of Kentucky Research Foundation and licensed to Control Delivery Systems, Inc. pursuant to the License Agreement By and Between University of Kentucky Research Foundation and Control Delivery Systems, Inc. dated October 31, 1995

3. US Patent No. 5,836,935 "Implantable Refillable Controlled release Device to Delivery Drugs Directly into an Internal Portion of the Body"

Owned by University of Kentucky Research Foundation and licensed to Control Delivery Systems, Inc. pursuant to the License Agreement By and Between University of Kentucky Research Foundation and Control Delivery Systems, Inc. dated September 9, 1997

4. US Patent No. 5,773,019 "Implantable Controlled Release Device to Delivery Drugs to an Internal Portion of the Body"

Owned by University of Kentucky Research Foundation and licensed to Control Delivery Systems, Inc. pursuant to the License Agreement By and Between University of Kentucky Research Foundation and Control Delivery Systems, Inc. dated September 9, 1997

5. US Patent No. 5,681,964 "Permeable Non-Irritating Prodrugs of non-steroidal, anti-inflammatory agents"

Owned by University of Kentucky Research Foundation and licensed to Control Delivery Systems, Inc. pursuant to the License Agreement By and Between University of Kentucky Research Foundation and Controlled Delivery Systems, Inc. dated September 9, 1997

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### EXHIBIT 16.2(v) LICENSOR DISCLOSEES

I. ALL OFFICERS, EMPLOYEES, AND CONSULTANTS OF LICENSOR AS OF THE AMENDMENT DATE

[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED. [\*]

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#### Execution Version

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# COLLABORATION AGREEMENT

#### BY AND BETWEEN

CONTROL DELIVERY SYSTEMS, INC.

AND

#### ALIMERA SCIENCES, INC.

DATED AS OF FEBRUARY 11, 2005

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 $[\,*\,]$  - INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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#### COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (the "Agreement") dated as of February 11, 2005 (the "Effective Date"), is made by and between CONTROL DELIVERY SYSTEMS, INC., a corporation organized and existing under the laws of the State of Delaware having its offices at 400 Pleasant St., Watertown, Massachusetts 02472 ("CDS"), and ALIMERA SCIENCES, INC., a corporation organized and existing under the laws of the State of Delaware having its offices at 6120 Windward Parkway, Alpharetta, GA 30005 ("Alimera"). CDS and Alimera are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

#### RECITALS

WHEREAS, CDS designs and develops innovative ophthalmic drug delivery products; and

WHEREAS, Alimera develops and commercializes ophthalmic drug products; and

WHEREAS, the Parties are interested in collaborating with one another and jointly funding the development, and sharing Net Profits from the sale, of novel products for treating eye diseases in humans, including a product for the treatment of diabetic macular edema using a corticosteroid; and

WHEREAS, CDS is willing to grant Alimera a license to certain of its proprietary technology and know-how relating to developing products for treating eye diseases and enter into such a collaboration upon the terms and conditions set forth below;

NOW THEREFORE, in consideration of the premises and of the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

#### ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the terms defined in this Article shall have the meanings specified below, whether used in their singular or plural form:

1.1 "Affiliate" shall mean any corporation or other entity that controls, is controlled by, or is under common control with a Party to this Agreement. A corporation or other entity shall be regarded as in control of another corporation or entity if it directly or indirectly owns or controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other entity.

1.2 "Alimera Improvements" shall mean any and all Improvements created, conceived or reduced to practice by Alimera, or its Affiliates, agents, subcontractors or sublicensees, alone or with others, or by Third Parties acting on their behalf, that are (a) Improvements covered by or derived from practice of the CDS Technology, and/or (b)

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Improvements covered by or derived from the practice of the Improvements set forth in clause (a); provided, however, that Alimera Improvements shall not include any Improvement that meets each of the following: (x) is related specifically to an active ingredient provided by Alimera and used in the Products, (y) can be practiced without infringing any CDS Existing Patent Rights and any Patent Rights included within CDS Improvements, or without utilizing any CDS Know-How, and (z) does not fall within the definition of the CDS Core Technology.

1.3 "Alimera Know-How" shall mean Know-How Controlled by Alimera.

1.4 "Alimera Patent Costs" shall mean fees and costs associated with filing, prosecution and maintenance of the Alimera-Prosecuted Patent Rights, as defined in Section 7.3, in the Territory.

1.5 "Approval" shall mean the approvals from applicable regulatory authorities in any country or region required to lawfully market a Product in such country or region, including, but not limited to, approval of an NDA. The term "Approved" shall mean the receipt of Approval.

1.6 "Bankruptcy Code" shall mean Title 11 of the United States Code, as amended from time to time.

1.7 "B&L" shall mean Bausch & Lomb Incorporated.

1.8 "B&L Agreement" shall mean the Amended and Restated License Agreement between CDS and B&L dated as of December 9, 2003 as in existence and effect on the Effective Date, a full and complete copy of which has been provided to Alimera.

1.9 "Business Day" shall mean each day of the week excluding Saturday, Sunday and U.S. federal holidays.

1.10 "CDS Core Technology" shall mean (a) any drug delivery device, or component thereof, for ophthalmic use that includes a core containing one or more drugs, and (b) any method or process for using a device described in clause (a).

1.11 "CDS Existing Patent Rights" shall mean (a) the United States and foreign patents and patent applications listed in Exhibit 1.11A, (b) any Patent Rights arising from those patents and patent applications during the Term, and (c) any other patents or patent applications Controlled by CDS as of the Effective Date, a Valid Claim of which, absent the licenses granted by CDS to Alimera under Section 5.1, would be infringed by the making, having made, using, selling, offering to sell or importing of a Product in the Collaboration Field by Alimera or its subcontractors or sublicensees as permitted under this Agreement; provided, however, that CDS Existing Patent Rights shall in no event include the patents and patent applications listed in Exhibit 1.11B or any Patent Rights arising from those patents or patent applications.

1.12 "CDS Improvements" shall mean any and all Improvements created, conceived or reduced to practice by CDS, or its Affiliates, agents, or sublicensees, alone or with others or by Third Parties acting on their behalf, during the course of activities conducted as set forth in the Development Plan, that are (a) Improvements covered by or derived from practice of the CDS Technology, and (b) Improvements covered by or derived from the practice of the Improvements

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set forth in clause (a); provided, however, that CDS Improvements shall not include any Improvement that is an Alimera Improvement.

1.13 "CDS Know-How" shall mean Know-How Controlled by CDS that is required for development and Commercialization of a Product.

1.14 "CDS Net Income" or "CDS Net Losses" shall mean, for the first calendar quarter after the CDS Profitability Date and for any calendar quarter thereafter, Net Sales by CDS, and/or CDS Sublicense Revenue actually received by CDS, for a Product in that calendar quarter minus the CDS Product Costs for such Product in that calendar quarter; provided that in the event any portions of the CDS Product Costs are already included in arriving at CDS Sublicense Revenue, such portions of the CDS Product Costs shall be excluded from the above calculation to determine the CDS Net Income or CDS Net Losses. To the extent Net Sales and/or CDS Sublicense Revenue actually received by CDS exceed the CDS Product Costs for the relevant calendar quarter, such amount of difference shall be deemed "CDS Net Income," and to the extent CDS Product Costs exceed Net Sales and/or CDS Sublicense Revenue actually received by CDS for the relevant calendar quarter, the amount of such difference shall be deemed "CDS Net Losses." For clarification, with respect to calculating CDS Net Income for any unit of Product, the Manufacturing Cost incurred to manufacture such unit shall be deemed to be incurred in that country and quarter in which such unit is sold.

1.15 "CDS Patent Costs" shall mean fees and costs associated with filing, prosecution and maintenance of the CDS-Prosecuted Patent Rights, as defined in Section 7.1.2, in the countries listed on Exhibit 1.15.

1.16 "CDS Patent Rights" shall mean CDS Existing Patent Rights and CDS' interest in any Patent Rights included within Alimera Improvements and CDS Improvements.

1.17 "CDS Product Costs" shall mean, with respect to a Product, all costs CDS incurred for developing and Commercializing such Product, including, without limitation, the following costs: (a) all Direct Development Costs incurred by CDS during the Term of this Agreement, (b) each of the following to the extent paid by CDS to Alimera pursuant to this Agreement: all Development Payments, Compounded Development Payments, Determined Disputed Costs and Compounded Disputed Payments, (c) each of the following, if any, owed by Alimera to CDS to the extent not already paid by Alimera: any Compounded Development Payments and Compounded Disputed Payments, plus any interest on such unpaid amount that has accrued in accordance with the terms of this Agreement after termination of either this entire Agreement or this Agreement with respect to a Product, as applicable, (d) each of the following to the extent not already included in Direct Development Costs or reimbursed by Alimera: CDS Patent Costs, UKRF Costs and insurance premiums paid by CDS to maintain insurance required by Section 10.4, as compounded, if applicable, pursuant to Section 4.4, and (e) any other costs incurred by CDS for developing and Commercializing such Product.

1.18 "CDS Profitability Date" shall mean, with respect to a Product, the first day of the first calendar quarter in which the aggregate of Net Sales by CDS, and CDS Sublicense Revenue actually received by CDS, of such Product for all preceding calendar quarters and the

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current calendar quarter exceeds the CDS Product Costs during all preceding calendar quarters and the current calendar quarter; provided that in the event that any portions of the CDS Product Costs are already included in arriving at the CDS Sublicense Revenue, such portions of the costs shall be excluded from the above calculation to determine the CDS Profitability Date. For clarification, all preceding calendar quarters include the Term of this Agreement and for any applicable periods thereafter.

1.19 "CDS Sublicense Revenue" shall mean any form of consideration (excluding any amounts paid for equity securities of CDS other than amounts that exceed the fair market value of such securities) in connection with a sublicense agreement that CDS enters into with a Third Party to sell or otherwise transfer some or all of CDS' rights to a Product, including, but not limited to, marketing rights and/or distribution rights, provided that (1) the fair market value of such securities shall be determined by mutual agreement of both Parties, and (2) in the event that the Parties fail to reach such mutual agreement, the matter shall be resolved by arbitration in accordance with Section 12.7.2 herein.

1.20 "CDS Technology" shall mean CDS Patent Rights, CDS Know-How and CDS' interest in Alimera Improvements and CDS Improvements.

1.21 "Change of Control" shall mean, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) except in the case of a bona fide equity financing in which a Party issues new shares of its capital stock, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's assets related to the Collaboration Field.

1.22 "Clinical IP" shall mean (a) all preclinical and clinical protocols, studies, data, results, study-related forms, materials and reports (e.g., investigator brochures, informed consent forms, data safety monitoring board related documents, patient recruitment related materials, biocompatibility studies, animal studies, safety studies, and chemistry, manufacturing and control data) resulting from any preclinical or clinical study or trial of any Product in the Collaboration Field that is conducted by or under the direction of Alimera or CDS, or their Permitted Subcontractors or sublicensees, pursuant to this Agreement, and any audit of any such preclinical or clinical study or trial, and (b) all INDs, NDAs, any unfiled applications, components or materials normally associated with an IND or NDA, regulatory filings or applications comparable to INDs or NDAs in any foreign jurisdictions, and other regulatory applications and Approvals regarding any Product in the Collaboration Field that are prepared or submitted by or under the direction of Alimera or CDS, or their Permitted Subcontractors or sublicensees, pursuant to this Agreement; provided, however, that Clinical IP shall not include any Pre-Existing Clinical IP.

1.23 "Clinical Supply Requirements" shall mean, with respect to each Product, the quantities of such Product that are required for the conduct of preclinical studies and clinical trials required to procure data necessary for the acceptance of filing of an NDA for the Product,

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pursuant to the Development Plan. For the avoidance of doubt, supplies for Non-NDA Trials are excluded from the definition of Clinical Supply Requirements.

1.24 "CODRUG(TM)" shall mean a compound or a pharmaceutically acceptable salt thereof comprising one constituent moiety covalently or ionically associated with at least one other constituent moiety, wherein each moiety, in its separate form (i.e., in the absence of the association), is a therapeutically or pharmacologically active agent or a prodrug or pharmaceutically acceptable salt of such an agent. The covalent association between said moieties can be either direct or indirect through a linker. Examples of covalent association include without limitation ester, amide, carbamate, carbonate, cyclic ketal, thioester, thioamide, thiocarbamate, thiocarbonate, xanthate, and phosphate ester bonds. Each constituent moiety of a CODRUG(TM) compound can be the same as or different from the other constituent moiety. Upon cleavage of the covalent or ionic association, the individual constituent moieties are reconstituted as the therapeutically or pharmacologically active forms of the same moieties prior to conjugation.

1.25 "Collaboration Field" shall mean the treatment and prevention of eye diseases in humans; provided, however, that the treatment and prevention of  $[\ast]$  is excluded from the Collaboration Field.

1.26 "Commercial Supply Requirements" shall mean, with respect to each Product, quantities of such Product that are required to fulfill requirements for commercial sales, Product sampling, and Non-NDA Trials, in the Collaboration Field in the Territory.

1.27 "Commercialize" or "Commercialization" shall mean any and all activities directed to marketing, promoting, Detailing, distributing, importing, offering for sale, having sold and/or selling a product, including, but not limited to, sampling, and conducting Non-NDA Trials.

1.28 "Commercialization Budget" shall have the meaning set forth in Section 4.2 hereof.

1.29 "Commercially Reasonable Efforts" shall mean efforts and resources that parties in the pharmaceutical industry would consider normal to use for a compound or product owned by a party in that industry or to which that party has rights, which is of similar market potential at a similar stage in its development or product life, taking into account the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, and other relevant factors. In determining Commercially Reasonable Efforts with respect to a particular Product, a Party may not consider any other product(s) owned or licensed by it.

1.30 "Compounded Development Payment" shall have the meaning set forth in Section 6.3.2 hereof.

1.31 "Confidential Information" shall have the meaning set forth in Section 8.1 hereof.

1.32 "Control" or "Controlled by" shall mean, in the context of a license to or ownership of intellectual property, possession of the ability on the part of a Party to grant access

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to or a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.

1.33 "Detail" shall mean a face-to-face meeting (including a live video presentation) with one or more healthcare professionals with prescribing authority during which scientific and/or medical information about the Product is discussed. Detailing does not include merely a reminder or a promotional sample drop. When used as a verb, the term "Detailing" shall mean to engage in the activity of a Detail.

1.34 "Development Budget" shall mean the initial Development Budget and thereafter each budget in the rolling three (3) year development plan agreed to by the Parties as described in Section 3.2 hereof.

1.35 "Development Plan" shall mean the initial Development Plan and thereafter each rolling three (3) year development plan agreed to by the Parties as described in Section 3.2 hereof. Each Development Plan (including the initial Development Plan) (a) shall set forth a strategy and plan for development (including, but not limited to, preclinical development and clinical trials), manufacturing and regulatory approval for each Product, shall indicate which Party shall have responsibility for the various development, and shall specified therein consistent with the other terms of this Agreement, and shall specify the expected timing of such activities, including the estimated dates of the initiation and completion of such activities, and (b) shall include a Development Budget as described in Section 3.2.

1.36 "Direct Commercialization Costs" shall mean only the following costs incurred, on a cash basis, by Alimera for Commercializing a Product in accordance with this Agreement and pursuant to the Commercialization Budget:

(a) Direct Costs of marketing activities for the Product, including pre-launch, launch, advertising, packaging, activities necessary for seeking and maintaining pricing and reimbursement approvals from Third Party payors, literature, lectures, training (including wet labs for training healthcare professionals) and sales promotion;

(b) [\*]

(c) Direct Costs associated with maintaining Approvals for the Product;

(d) Direct Costs of package development and package maintenance for the Product;

(e) Selling Expenses for the Product;

(f) Manufacturing Costs to satisfy Commercial Supply Requirements for the Product;

(g) Direct Costs of distribution of the Product other than the costs specified in Section 1.60(d);

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(h) Royalties, milestones and other fees paid by Alimera under Third Party license(s) [\*] that are at arms' length to the extent they relate to the Product, to the extent such licenses are necessary for Alimera to make, have made, use, offer to sell, sell, and import the Product without infringing patents of such Third Parties, including without limitation as provided for in Section 7.6.4;

 (i) Direct Costs of selection, filing, prosecution and maintenance of trademarks used solely for the Product (or an appropriate allocation in the case of any trademarks used for the Product and other products);

(j) Direct Costs of Medical Advisory Services for the Product;

(k) Recall expenses that are Direct Commercialization Costs as set forth in Section 4.6;

(1) Product Liability Losses that are Direct Commercialization Costs as set forth in Section 10.5;

(m) Insurance premiums paid by Alimera for the insurance required by Section 10.4 to the extent such insurance relates to Commercialization of the Product (i.e., if insurance covers risks other than risks related to Commercialization of the Product, then only an appropriate portion of such premiums shall be included); and

(n) Taxes, duties, tariffs and other governmental charges (excluding taxes on income) associated with manufacture and distribution of the Product, to the extent not deducted from Net Sales pursuant to Section 1.60(c).

Notwithstanding any other provisions in this Agreement, Direct Commercialization Costs shall include only the costs of labor for those individuals who spent greater than fifty percent (50%) of their time on activities within the Commercialization Budget during any calendar month (the "Majority Time Individuals"), and such costs shall be determined according to the amount of the Majority Time Individuals' time actually spent on such Commercialization activities, provided that, if the Commercialization activity is Detailing, then such costs for the Majority Time Individuals shall be determined in accordance with Section 1.81. In the event there is more than one Product on the market at any given time, Direct Commercialization Costs attributable to more than one Product shall be allocated to each Product as appropriate; provided, however, that in no event shall any Direct Commercialization Costs be accounted for more than once. Notwithstanding the foregoing, in the event that a person devotes time to activities under both the Commercialization Budget and the Development Plan, the time spent shall be aggregated in determining whether such person meets the fifty percent (50%) threshold set forth in this definition and in the definition of Direct Development Costs, and the person's time shall be allocated accordingly between development and Commercialization.

1.37 "Direct Costs" shall mean, on a cash basis, the costs of labor (including only salaries, wages and current period employee benefits (but specifically excluding expenses associated with stock options or other equity-based or deferred compensation)), raw materials, supplies, services, fees, and other resources, directly and exclusively consumed or used in the conduct of the applicable activity; provided, however, that the following costs shall not be

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deemed Direct Costs: (i) corporate overhead expenses, including, but not limited to, general administration, business development, travel, entertainment, executive management, facilities, finance, information system and data management services, investor relations, human resources, legal, payroll, purchasing, and corporate supervisory services; (ii) amortization and depreciation expenses, interest expenses, taxes, extraordinary or nonrecurring losses customarily deducted by a Party in calculating and reporting consolidated net income, capital expenditures (including, but not limited to, purchases of facilities, property or equipment), and inventory write-offs (to the extent not attributable to a Product); (iii) consulting (including legal) fees unless specifically set forth in a mutually approved budget; and (iv) payments made to any related party or Affiliates in excess of an arm's length charge for the relevant product or service.

1.38 "Direct Development Costs" shall mean the following costs incurred, on a cash basis, by either Party for developing a Product, to the extent set forth in the Development Budget approved by the Parties:

(a) Direct Costs for development activities for the Product, incurred, on a cash basis, by a Party or paid by a Party to Permitted Subcontractors, conducted pursuant to the Development Plan, including, but not limited to, research, formulation development and testing, clinical development activities, data management, toxicology, and planning and execution of clinical trials required to procure data necessary for the acceptance of filing of an NDA;

(b) Manufacturing Costs to satisfy Clinical Supply Requirements;

(c) Direct Costs for regulatory filings pursuant to the Development Plan (specifically excluding any filing related to Non-NDA Trials) for the Product;

(d) Insurance premiums paid by either Party for commercial insurance to the extent such insurance relates to development activities conducted pursuant to the Development Plan in accordance with Section 10.4 hereof (i.e., if insurance covers risks other than risks related to development of the Product, then only an appropriate portion of such premiums shall be included);

(e) CDS Patent Costs paid from the Effective Date up to the first Product Profitability Date that are not otherwise reimbursed by a Third Party; provided, however, that CDS Patent Costs in excess of [\*] in any calendar year shall not be included as Direct Development Costs;

(f) Direct Costs of the activities conducted under Section 3.11, including, but not limited to, technology transfer assistance from CDS to Alimera to enable Alimera to manufacture the Product for Commercialization;

(g) Direct Costs for capital expenditures to the extent attributable to the Product as specifically approved in the Development Plan and set forth in the Development Budget; and

(h) Other Direct Costs as described in the Development Plan and set forth in the Development Budget.

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Notwithstanding any other provisions in this Agreement, Direct Development Costs shall (1) with the exception of (e) and (f) above, include only Direct Costs incurred, on a cash basis, in connection with activities conducted to procure data necessary for the acceptance of filing of an NDA for the Product; and (2) include only the costs of labor for those individuals who spent greater than fifty percent (50%) of their time on activities under the Development Plan during any calendar month, and such costs shall be determined according to the percentage of the individuals' time actually spent on such development activities; and (3) not include any Commercialization costs. Notwithstanding the foregoing, in the event that a person devotes time to activities under both the Commercialization Budget and the Development Plan, the time spent shall be aggregated in determining whether such person meets the fifty percent (50%) threshold set forth in this definition and in the definition of Direct Commercialization Costs, and the person's time shall be allocated accordingly between development and Commercialization.

1.39 "DME" shall mean diabetic macular edema.

1.40 "Effective Date" shall mean the date first set forth above.

1.41 "Earnest Money Loan" shall mean the aggregate of the loan under the Secured Promissory Notes from CDS to Alimera dated October 19, 2004, November 18, 2004 and December 22, 2004.

1.42 "Excluded Product" shall mean a [\*] that generally conforms to the drawings and specifications (and any prior iterations thereof in whole or in part) shown in Exhibit 1.42.

1.43 "FDA" shall mean the United States Food and Drug Administration or any successor agency with responsibilities comparable to those of the United States Food and Drug Administration.

1.44 "First Commercial Sale" shall mean, with respect to each Product, the first sale for use or consumption by the general public of such Product in a country after required Approval has been granted by the applicable regulatory authority of such country.

1.45 "First Product" shall have the meaning set forth in Section 1.77 hereof.

1.46 "GAAP" shall mean the current United States generally accepted accounting principles, consistently applied.

1.47 "Gross Sales" shall mean, for any period, on a cash basis (a) for any arm's length transaction in which Products are sold separately by Alimera or its Affiliates to a Third Party, the gross invoice price for Products in such transactions, and (b) for all other transactions (i.e., other than those described in subsection (a)) in which Products are sold, used or otherwise disposed of by Alimera or its Affiliates (including in barter or similar transactions, or transactions that are not at arm's length to a Third Party, or transactions in which Products are not sold separately, but not including the provision of Products intended for use solely as samples), the total imputed sales price for Products in such transactions, using as the imputed sales price the weighted

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average gross invoice price for Products under subsection (a) during the preceding calendar quarter or, if there have been no Gross Sales under subsection (a) in the preceding quarter, using a reasonable imputed price to be determined at the time by the parties. For purposes of this Section 1.47, "sold separately" shall mean sold, solely for monetary consideration, on a stand-alone basis (i.e., with a selling price independent of any other product) for not less than arm's length value.

1.48 "Improvements" shall mean any and all Inventions, enhancements, derivatives, new uses, developments, techniques, materials, compounds, products, designs, processes or other technology or intellectual property, whether or not patentable and all Patent Rights and other intellectual property rights in any of the foregoing.

1.49 "IND" shall mean the Investigational New Drug Application filed with FDA or a similar application filed with an applicable regulatory authority outside of the United States.

1.50 "Invention" shall mean ideas, information, Know-How, data research results, writings, inventions, discoveries, modifications, improvements and other technology (including, but not limited to, any proprietary biological or other materials, compounds or reagents and computer software), whether or not patentable or copyrightable.

1.51 "Joint Development Team" or "JDT" shall mean the body organized and acting pursuant to Article 2 hereof.

1.52 "Know-How" shall mean unpatented information, whether or not patentable, including, but not limited to, technical information, processes, formulae, trade secrets, materials, designs, drawings and data.

1.53 "Majority Time Individuals" shall have the meaning set forth in Section 1.36.

1.54 "Manufacturing Costs" shall mean:

(A) with respect to Product manufactured by a Third Party, a Party's cost of procuring such Product on an arms' length basis; or

(B) with respect to Product manufactured by a Party or one of its Affiliates, (1) Direct Costs incurred, on a cash basis, by such Party or one of its Affiliates to manufacture such Product, including Direct Costs of purchasing, inspection, quality assurance, quality control, storage, scrap and training, and (2) a portion of depreciation, amortization, interest expense, utilities, rent, maintenance and repairs, insurance and other manufacturing overhead (the "Manufacturing Overhead") allocable to Product as determined by the following formula: the Manufacturing Overhead multiplied by a fraction, the numerator of which is the number of direct labor hours of individuals who spent time on the production of Product at a plant at which Product is manufactured, and the denominator of which is the number of direct labor hours devoted to the production of all products at such plant when the plant is operating at full capacity, provided that Manufacturing Costs shall exclude costs associated with excess capacity, selling costs (including, without limitation, marketing, advertising, salaries and commissions), corporate overhead, costs that are otherwise attributed as Direct Development Costs or Direct Commercialization Costs under this Agreement, royalties (earned or paid up) and other amounts

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payable to Third Parties under any license taken by a Party in connection with the manufacture of the Product, and all amounts spent on research and development;

provided, however, that any amount determined pursuant to clause (B) shall not exceed the amount that a qualified Third Party manufacturer would charge for supplying comparable quantities of the relevant Product in a timely manner on reasonable and customary terms and conditions.

1.55 "Medical Advisory Services" shall mean those health care professionals employed or engaged by a Party with sufficient medical or other pertinent health care experience to engage in in-depth dialogues with physicians regarding medical issues associated with a Product.

1.56 "Milestone Payment" shall have the meaning set forth in Section 6.2 hereof.

1.57 "NDA" shall mean a new drug application or product license application or its equivalent filed with and accepted by the FDA after completion of human clinical trials to obtain marketing approval for a Product, or any comparable application filed with and accepted by the regulatory authorities of a country other than the United States, including, where applicable, any applications for governmental pricing and marketing approval.

1.58 "Net Profits" or "Net Losses" shall mean, for a particular calendar quarter, the Net Sales for a Product in a country minus the Direct Commercialization Costs for such Product in that country. For the avoidance of doubt, Net Profits shall be calculated on a Product-by-Product and calendar quarter-by-quarter basis. To the extent Net Sales exceed Direct Commercialization Costs for the relevant calendar quarter, such amount of difference shall be deemed "Net Profits," and to the extent Direct Commercialization Costs exceed Net Sales for the relevant calendar quarter, such amount of difference shall be deemed "Net Losses." For clarification, with respect to calculating Net Profits or Net Losses for any unit of Product, the Manufacturing Cost incurred to manufacture such unit shall be deemed to be incurred in the country and quarter in which such unit is sold.

1.59 "Net Profits Payment" shall have the meaning set forth in Section 6.5.1(b) hereof.

1.60 "Net Sales" shall mean, with regard to a Product, on a cash basis, for any period, Gross Sales less the following reasonable and customary deductions:

(a) normal and customary trade, cash and other discounts, allowances and credits allowed and actually taken directly with respect to sales of the Product;

(b) credits or allowances actually granted for damaged goods or returns or rejections of the Product;

(c) taxes or other governmental charges imposed directly on the sales of Products, including value added taxes or other similar governmental charges, but not including any tax levied with respect to income;

(d) freight, postage, shipping, and insurance charges; and

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(e) charge back payments and government rebates allowed and taken.

1.61 "Non-NDA Trial" shall mean any clinical trial, or part of a clinical trial, of a Product that is not designed or required to procure data necessary for the acceptance of filing of an NDA. Non-NDA Trials may be conducted before or after the filing of an NDA, before Approval or at any time after Approval. Non-NDA Trials shall specifically not include (that is, costs associated with such trials may be deemed Direct Development Costs) any (i) clinical trials designed to obtain favorable labeling at the time of initial Approval pursuant to the Development Plan, (ii) post-Approval or post-marketing trials required by the FDA or other regulatory authority in granting a conditional Approval, or (iii) trials are prior or subsequent to the filing of an NDA or Approval.

1.62 "Non-Paying Party" shall have the meaning set forth in Section 6.3.2 hereof.

1.63 "Option Compound" shall mean a compound, other than a compound that is a corticosteroid, that (i) Alimera has a right to use and (ii) is selected by Alimera under an Alimera Compound Option set forth in Section 5.8; provided, however, that Option Compound shall not include any compound that is included in a license or option by CDS to a Third Party, or is included in a term sheet with a Third Party, as of the date on which Alimera notifies CDS under Section 5.8 that Alimera wishes to exercise an Alimera Compound Option with regard to such compound. For the avoidance of doubt, a "compound," as used herein, shall be a specific compound and shall not be a category or class of compounds.

1.64 "Option Product" shall mean (i) a product that meets the definition of "Product" in Section 1.77, except that the term "Option Compound" shall be substituted in place of "corticosteroid," and (ii) clause (B)(2) and the third sentence of Section 1.77 shall be omitted.

1.65 "Option Term" shall mean the period commencing on the Effective Date and expiring on the earliest of (i) [\*] months after the Effective Date; (ii) the date on which [\*]; and (iii) Alimera's exercise of all [\*] Alimera Compound Options under Section 5.8.

1.66 "Owed Party" shall have the meaning set forth in Section 6.3.2 hereof.

1.67 "Party" shall mean CDS or Alimera.

1.68 "Patent Rights" shall mean any United States or foreign patent or patent applications, any patents issuing from such patent applications, and any continuations, continuations-in-part to the extent specifically directed to subject matter specifically described in such patent applications, divisionals, renewals, reexaminations, reissues, extensions or provisional applications of any of the foregoing and any corresponding patent, patent application, utility model, inventor certificate, registration or the like in any country of the world with respect to the foregoing.

1.69 "Permitted Subcontractor" shall mean a Third Party or an Affiliate that has been awarded a subcontract with one Party in accordance with Section 3.7 hereof.

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1.70 "Phase I Clinical Trial" shall mean a clinical trial as defined in 21 C.F.R. 312.21(a), as may be amended from time to time, or any foreign equivalent thereto.

1.71 "Phase I/II Clinical Trial" shall mean a combined Phase I Clinical Trial and Phase II Clinical Trial.

1.72 "Phase II Clinical Trial" shall mean a clinical trial as defined in 21 C.F.R. 312.21(b), as may be amended from time to time, or any foreign equivalent thereto.

1.73 "Phase III Clinical Trial" shall mean a clinical trial as defined in 21 C.F.R. 312.21(c), as may be amended from time to time, or any foreign equivalent thereto.

1.74 "Pre-Existing Clinical IP" shall mean [\*].

1.75 "Primary Contact Person" shall have the meaning set forth in Section 3.4.

1.76 "Prime" shall have the meaning set forth in Section 6.5.1(b).

1.77 "Product" shall mean a drug delivery device that meets all of the following criteria: (A) it has a core within a polymer layer that contains a drug in a form other than a CODRUG(TM) and no other active ingredient, where the core does not include a CODRUG(TM), (B) it is Approved or designed to be Approved (1) to deliver a corticosteroid and no other active ingredient by implantation, injection, or other direct delivery method to the posterior portion of the eye, or (2) to treat DME by delivering a compound or formulation by implantation, injection, or other direct delivery method other than through an incision smaller than that required for a 25 gauge needle, (C) it does not fall under the definition of Excluded Product, and (D) it is Approved or designed to be Approved for a particular indication in a particular country. For clarification, eye drops or other topical administration and tablets or other oral administration shall not be deemed to be direct delivery to the posterior portion of the eye. For example, "Product" shall specifically include a drug delivery device that meets all of the following criteria (such product sometimes referred to as the "First Product"): (1) consists of [\*] (2) is Approved or designed to be Approved to be administered [\*]; (3) is Approved or designed to be Approved [\*] and (4) is Approved or designed to be Approved for a particular indication in a particular country. For clarification, with regard to the same drug delivery device described above, each indication in each country shall be a separate Product. By way of non-limiting examples, with regard to a particular drug delivery device X, (i) X for DME and X for age-related macular degeneration shall be two different Products, and (ii) X for DME in the United States and X for DME in Japan shall be two different Products.

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1.78 "Profitability Date" shall mean, with respect to each Product, the first day of the first calendar quarter in which Net Profits are realized for such Product.

1.79 "Recall" shall mean any recall of a product or any related actions (e.g., market withdrawal and stock recovery). For avoidance of doubt, Recall includes recall of product packaging.

1.80 "Right of Access to Clinical IP" shall mean the right to reference, cross-reference, review, have access to, incorporate and use Clinical IP in any regulatory applications or filings, any patent filings, or for any research or development purpose.

1.81 "Selling Expenses" shall mean Direct Costs incurred, on a cash basis, by Alimera for the sales force who are employees of Alimera or its Affiliates, all only pursuant to the Commercialization Budget; provided, however, that if a portion of time of Alimera Majority Time Individuals involved in Detailing Products is devoted to Detailing products other than Products, then only the following percentages of the Alimera Majority Time Individuals' time spent in Detailing shall be Direct Commercialization Costs:

(a) [\*] if the Product is carried in the sole Detail position, in which the Product is the only product presented during a Detail and the key Product attributes are verbally presented in a presentation delivered during the Detail by Alimera's or its Affiliates' sales representative;

(b) [\*] if the Product is carried in the primary Detail position, in which key Product attributes are verbally presented in the first position during a Detail, where the Product is given primary emphasis (i.e., an emphasis that is more important than the emphasis given to any other product presented), and where no more than three products are presented during such Detail;

(c) [\*] if the Product is carried in the secondary Detail position, in which key Product attributes are presented in the second position during a Detail, where the Product is given significant but not primary emphasis, and where no more than three products are presented during such Detail;

(d) [\*] if the Product is carried in the tertiary Detail position, in which key Product attributes are presented in the third position during a Detail, where the Product is given some emphasis, and where three products are presented during such Detail; provided that (1) if more than one Product is the subject of a Detail, the foregoing percentages shall be cumulative, not to exceed 100% (e.g., if one Product is carried in the primary Detail position and another Product is carried in the secondary Detail position, then  $\left[ \star \right]$  of the sales force time shall be a Direct Commercialization Cost with respect to the first Product and [\*] shall be a Direct Commercialization Cost with respect to the second Product), and (2) if there are more than three products presented in a Detail, the percentages specified in (b)-(d) above shall be multiplied by a fraction, the numerator of which is three and the denominator of which is the number of products presented in that Detail (e.g., if a Product is carried in the secondary Detail position and there are four products presented during such Detail, then [\*] is multiplied by -3/4 and [\*] of the sales force time shall be a Direct Commercialization Cost with respect to that

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Product). For clarification, the costs of Majority Time Individuals shall be determined according to the amount of Majority Time Individuals' time actually spent on Detailing multiplied by the applicable percentage as specified in this Section 1.81 above. For example, if a Majority Time Individual spends twenty-five (25) hours on Detailing, in which Products are carried in the primary Detail positions, then Direct Commercialization Costs attributable to such Detailing shall be the Direct Costs of 25 hours multiplied by [\*] (as may be further adjusted as specified above). For further clarification, Selling Expenses relating to a Product may be incurred prior to First Commercial Sale of such Product (e.g., for sales force training); in such event, the percentages referred to in this Section 1.81 initially shall be based on the Detail position for the relevant Product contemplated in the Commercialization Budget. For example, if the Product is projected in the Commercialization Budget to be the sole product Detailed by the sales force, then initially [\*] of the Direct Costs associated with the sales force shall be allocated as Selling Expenses. In the event that the actual Detail position for a Product differs from that projected in the Commercialization Budget, then the amount of the Direct Costs that are included as Direct Commercialization Costs shall be adjusted subsequently to reflect the actual Detail position.

1.82 "Term" shall have the meaning set forth in Section 11.1.

1.83 "Territory" shall mean all countries and territories worldwide.

1.84 "Third Party" shall mean any person or entity other than CDS, Alimera or their respective Affiliates.

1.85 "UKRF" shall mean the University of Kentucky Research Foundation.

1.86 "UKRF Costs" shall mean all royalties, milestones and other fees due to UKRF related to a Product pursuant to the UKRF Licenses.

1.87 "UKRF Licenses" shall mean the licenses set forth in Exhibit 1.87, as may be amended from time to time consistent with Section 7.9, full and complete copies of which agreements in effect as of the Effective Date have been provided to Alimera.

1.88 "Valid Claim" shall mean a claim of an issued and unexpired patent, or a claim of a pending patent application, which has not been withdrawn, cancelled, abandoned, disclaimed, or held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal.

#### ARTICLE 2 JOINT DEVELOPMENT TEAM

2.1 Establishment of Joint Development Team. The Parties shall establish a Joint Development Team ("JDT"), which shall consist of a total of four members, with two members from each Party. Members of the JDT may be represented at any meeting by a designee appointed by such member for such meeting, provided that reasonable advance notice is provided to the other Party and such designee shall be subject to an appropriate confidentiality agreement. Each Party shall be free to change its members on prior written notice to the other Party. Each Party may, in its discretion, upon reasonable notice to the other Party, invite non-

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JDT employees and consultants of such Party to attend such meeting, provided that such non-JDT employees and consultants shall be subject to appropriate confidentiality agreements. The JDT shall remain in place until the expiration or termination of its responsibilities set forth in this Agreement.

2.2 Responsibilities of the Joint Development Team. In addition to the responsibilities expressly described elsewhere in this Agreement, the JDT shall:

 (a) draft the Development Plan and present it to the Parties for approval and monitor development activities and execution of the development activities under the Development Plan;

(b) develop updates or amendments to the Development Plan, and the Development Budget, including, but not limited to, the annual updates pursuant to Section 3.2, and make recommendations to the Parties for approval by the Parties of such updates or amendments;

(c) quarterly review and evaluate progress under the Development Plan; provided, however, that the JDT shall not have authority to make any determination that either Party is in breach of its obligations under the Development Plan;

(d) attempt to settle disputes or disagreements that are unresolved by the Primary Contact Persons; provided, however, that the JDT shall not have authority to make any determination that either Party is in breach of its obligations under the Development Plan; and

(e) perform any other activities related to the Development Plan as jointly requested by both Parties from time to time.

For the avoidance of doubt, the JDT shall have no authority to amend either this Agreement or the Development Plan.

2.3 Meetings; Minutes. During the course of implementing the Development Plan, the JDT shall meet at least once each calendar quarter, and more frequently as the Parties mutually agree is appropriate, on such dates, in such places and at such times as the Parties shall agree. The meetings shall alternate between the offices of the Parties unless the Parties otherwise agree. Meetings may be by teleconference or videoconference; provided, however, that the JDT shall meet in person at least twice every calendar year during the course of implementing the Development Plan. In addition to these required meetings, the JDT may also be polled or consulted from time to time by means of telecommunications, video conferences or correspondence, as deemed necessary or appropriate in order to fulfill its obligations under this Agreement. The JDT will be chaired by CDS until June 30, 2005 and by Alimera during the second half of 2005, and the chairmanship of the JDT shall alternate between the Parties semi-annually thereafter. The role of the chairperson shall be to convene and preside at meetings of the JDT, but the chairperson shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote. Not later than thirty (30) days after the Effective Date, the JDT shall hold an organizational meeting. Reasonably detailed written minutes will be kept of all JDT meetings and will reflect without limitation material decisions made at such meetings. The chairperson of the JDT shall have responsibility for keeping minutes. Draft meeting minutes will be sent to each

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member of the JDT for review and approval within ten (10) Business Days after a meeting. Minutes will be deemed approved unless a member of the JDT objects to the accuracy or completeness of such minutes within thirty (30) calendar days of receipt.

2.4 Decision-Making and Dispute Resolution. From the Effective Date until the termination of the Development Plan, neither Party shall undertake development of a Product except in accordance with the Development Plan or as otherwise permitted by Section 6.3.3. The representatives of each Party shall have collectively one vote on behalf of such Party; provided, however, that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. The JDT shall operate by unanimous consent, provided that any deadlock shall be resolved as follows: in the case of any matter which cannot be resolved by the JDT, including, but not limited to, disputes referred to the JDT by the Primary Contact Persons pursuant to Section 3.4 hereof, at the written request of either Party, the issue shall be referred to senior management of the Parties in accordance with Section 12.7. The JDT shall meet to consider any dispute referred to it pursuant to Section 3.4 within fifteen (15) days of such referral and at the conclusion of such meeting shall either (1) have resolved the dispute and report such resolution in writing to the Parties or (2) refer the matter for resolution as set forth in the preceding sentence. If such executives cannot resolve such matter within the relevant time period, the matter shall be resolved in accordance with the following provisions:

(a) If the deadlock relates to subject matter (other than subject matter that would have an impact on the Development Budget, Direct Development Costs and/or the reconciliation of Direct Development Costs) for which one Party has the primary responsibility as set forth in Sections 3.2.3 and 3.2.4, that Party shall have the right to resolve the deadlock in its reasonable determination; and

(b) If the deadlock relates to subject matter that would have an impact on the Development Budget, Direct Development Costs and/or the reconciliation of Direct Development Costs, or to subject matter for which neither Party has the primary responsibility under Sections 3.2.3 and 3.2.4, then the matter may be referred to arbitration in accordance with Section 12.7.2 hereof.

2.5 Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members, designees and non-JDT invitees to attend meetings of, and otherwise participate on, the JDT, and such costs and expenses shall not be Direct Development Costs or Direct Commercialization Costs but time spent in connection with such meetings shall be treated as time devoted to development in determining whether a person devotes at least 50% of his time to development and/or Commercialization activities.

2.6 Dissolution of JDT. Upon the mutual agreement of the Parties, the activities and obligations of the JDT and its members may be suspended until such time as (1) active development is being undertaken, or contemplated to be undertaken, under the Development Plan, or (2) the JDT is dissolved.

ARTICLE 3 DEVELOPMENT ACTIVITIES

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3.1 General. CDS and Alimera shall undertake development activities for the Products in the Collaboration Field in accordance with the Development Plan. During the course of implementing the Development Plan, CDS and Alimera shall communicate regularly and shall assume certain rights and responsibilities for the development of the Products in the Collaboration Field in accordance with Section 3.2.3 and the Development Plan, all as described more specifically herein.

#### 3.2 Development Plan.

3.2.1. Initial Development Plan. No later than thirty (30) days after the Effective Date, the Parties will approve an initial Development Plan for the First Product. Such Development Plan will describe in reasonable detail the activities to be undertaken by each of the Parties for the period commencing on the Effective Date and ending on December 31, 2007, and shall be appended hereto as Exhibit 3.2 and incorporated herein by reference. In the event that an initial Development Plan is not approved within 30 days after the Effective Date, either Party may terminate this Agreement in accordance with Section 11.4.

3.2.2. Annual Updates. Not later than September 30 of each year during the course of implementing the Development Plan and commencing on September 30, 2005, the Parties shall agree to an update to the Development Plan, describing in reasonable detail the activities to be undertaken during the next three (3) calendar years and the expected timing of such activities, including the estimated dates of the initiation and completion of such activities (which may be adjusted by the Parties as necessary). For example, the annual update taking place on or before September 30, 2005 will describe development activities and the expected timing for such activities for calendar years 2006, 2007 and 2008. The most recently updated Development Plan shall be incorporated into Exhibit 3.2 and shall be deemed the Development Plan for the applicable time period. The initial Development Plan and each updated Development Plan shall (a) reflect Commercially Reasonable Efforts to be undertaken by the Parties to develop Products, and (b) include a Development Budget, which sets forth, for the time period covered by the applicable Development Plan, on a calendar quarter-by-quarter and Product-by-Product basis, the budget for development of each Product during the applicable time period. The Development Budget shall also specifically allocate the Direct Development Costs to be incurred by CDS and by Alimera for the period covered in the Development Budget, broken down on a calendar quarter-by-quarter and Product-by-Product basis. At any time during the course of development, upon mutual written agreement, the Parties may amend the Development Plan, including, but not limited to, the Development Budget. In the event the Parties fail to agree to an updated Development Plan, the Parties shall refer the matter to dispute resolution in accordance with Section 12.7 and shall proceed in accordance with the then existing Development Plan until the matter is resolved; provided, however, that if the dispute relates to costs proposed by a Party to implement an agreed to Development Plan, then the Parties shall proceed in accordance with Section 6.3.3.

Each Development Budget shall be prepared on a cash basis, shall provide a level of detail that is reasonably consistent with the initial Development Budget, and shall provide a greater level of detail for the immediately succeeding calendar year than for the remaining two (2) calendar years.

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3.2.3. Allocation of Responsibility for Development Activities. The Parties acknowledge and agree that each Development Plan shall allocate primary responsibility for the various activities (and any related or ancillary activities) listed below to be performed by the responsible Party as follows:

	Activity	Responsible Party
Α.	Preclinical research and development, including Product design, formulation, preclinical safety studies and in vivo pharmacology studies	CDS
-		
в.	Technology transfer as described in Section 3.11	CDS
C.	Phase I, Phase I/II, Phase II and Phase III Clinical Trials, as needed to procure data necessary for the acceptance of filing of an NDA	Alimera
D.	Preparation, filing and maintenance of regulatory filings including, but not limited to, NDA, but excluding the CDS IND (defined below in Section 3.2.4)	Alimera
E.	Filing and maintenance of the CDS IND (defined below in Section $3.2.4$ )	CDS
F.	Manufacturing for Clinical Supply Requirements	CDS
G.	Filing, prosecution and maintenance of CDS Patent Rights (subject to Alimera's rights in Article 7)	CDS

For clarification, commercial manufacturing is Commercialization for which Alimera has primary responsibility as set forth in greater detail in Article 4.

- 3.2.4. Regulatory Approvals.
- (a) Regulatory Filings.

(i) The CDS IND. Alimera and CDS shall be jointly responsible for preparing, and CDS shall be responsible for submitting (in the name of CDS), an IND in the United States (the "CDS IND") for the first Product. CDS shall have primary responsibility and final decision-making authority for all regulatory matters related to the CDS IND, including communicating with the FDA about such IND. CDS shall have final decision-making authority for all clinical trials conducted pursuant to such IND. Together with the CDS IND, CDS shall submit to the FDA a letter in form and substance satisfactory to both Parties authorizing a person designated by Alimera and reasonably acceptable to CDS (initially, [\*]) to communicate directly with the FDA regarding the CDS

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IND. In exercising its right to communicate directly with the FDA related to the CDS IND, (1) Alimera shall not propose any change, or accept any FDA proposals for any change, or make any other decisions, with respect to the CDS IND, (2) if Alimera wishes to initiate communications with the FDA, Alimera shall afford a representative of CDS the opportunity to participate in all such communications, provided that  $\ensuremath{\mathtt{CDS}}$ may decline such participation, and (3) if the FDA initiates unsolicited communications with Alimera, Alimera shall use Commercially Reasonable Efforts to afford a representative of CDS the opportunity to participate in all such communications, provided that CDS may decline such participation. In the event that CDS does not participate in any such communication with the FDA, Alimera shall, as soon as possible, but no later than two (2) Business Day after such communication, report to CDS the occurrence of such communication and provide CDS with a reasonably detailed summary of the content of the communication. In the event that the Parties have disagreement prior to, during, or after such communications, CDS shall have the final decision-making authority.

(ii) Other Regulatory Filings. When sufficient preclinical data are available from preclinical studies for the first Product conducted pursuant to the Development Plan, Alimera shall have the right and responsibility for filing an IND (in the name of Alimera) including such preclinical data but not including any Pre-Existing Clinical IP. No later than seven days after FDA issues a letter authorizing Alimera's IND, CDS shall request approval from FDA for transferring (1) its clinical protocol for the first Product, and (2) responsibility for the patients in its clinical studies for the first Product, to Alimera's IND. Promptly after receiving such approval from the FDA, and in accordance with any other legal requirements, CDS shall effect such transfer as approved and CDS shall thereafter withdraw the CDS IND. Unless otherwise agreed by the parties, Alimera shall be responsible for all subsequent and non-U.S. regulatory matters, including filing an NDA, provided that no regulatory filings by Alimera shall include any Pre-Existing Clinical IP. Alimera shall be responsible for obtaining Approvals and for subsequent maintenance of Approvals. For regulatory filings made in the name of Alimera, Alimera shall have the primary authority and responsibility, with input from CDS, for submitting supplements, communications, annual reports, adverse event reports, manufacturing changes, supplier designations and other related filings, and for communicating with FDA. The Party responsible for submitting regulatory filings (the "Regulatory Submission Party") shall provide the other Party (the "Regulatory Non-Submission Party") with copies of all substantive submissions to (which may be in draft form), and all correspondences from, the FDA or other regulatory authorities. The Regulatory Non-Submission Party may provide comments regarding such submission prior to such planned submission, and the Regulatory Submission Party shall consider in good faith incorporating into the planned submission any such comments. The Regulatory Non-

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Submission Party shall supply Know-How necessary to obtain Approvals for each Product.

(b) Manufacture-related Activities. Alimera shall be responsible for preparing and submitting all documentation to regulatory authorities regarding the manufacture of the Product for commercial sale necessary to obtain Approvals for such Product. Alimera shall be responsible for all activities related to pre-Approval inspections of Alimera's (or its subcontractor's) manufacturing facility. Each Party shall have the right to inspect and audit the other Party's manufacturing facility and related records and its operations, upon reasonable notice. Any information obtained by a Party during such visits shall be treated as Confidential Information in accordance with Article 8 of this Agreement.

(c) Documentation. Each Party shall maintain all records, including, but not limited to, batch records and supporting documentation required by the FDA and other applicable regulatory authorities with respect to each Product for the periods of time required by such authorities and shall provide a copy of all such records to the other Party within ten (10) Business Days of reasonable request by the other Party. Each Party shall provide the other Party with reasonable access to documents and other materials Controlled by the other Party that are useful in the regulatory filings and maintenance of Approvals in the Territory.

(d) Reporting. Each Party shall use Commercially Reasonable Efforts to immediately provide notice to the other Party (and shall in any event provide such notice within five (5) days) of: (a) discovery by such Party of any event that triggers a filing requirement with FDA or other regulatory authorities; and (b) any requirements that FDA may impose with respect to the Approval (including, but not limited to, additional clinical trials) and all FDA inquiries requiring a response.

(e) Meetings. In connection with Section 3.2.4 (a)-(d) above, the Regulatory Submission Party shall provide the Regulatory Non-Submission Party with notice of all meetings, conferences, and discussions (including, but not limited to, advisory committee meetings and any other meeting of experts convened by FDA or other regulatory authorities concerning any topic relevant to the Product) scheduled with FDA or such other regulatory authorities concerning any regulatory matters relating to the Product within one (1) Business Day after the Regulatory Submission Party receives notice of the scheduling of such meetings, conferences, or discussions. The Parties shall jointly prepare for and participate in such meetings, conferences or discussions. The Parties shall confer in advance on the scheduling of, the objectives to be accomplished at, and the agenda and strategy for, such meetings, conferences, and discussions with FDA or other regulatory authorities. In the event that the Parties have disagreement relating to such meetings, conferences and discussions, the Regulatory Submission Party shall have the final decision-making authority.

3.3 Performance.

3.3.1. Commercially Reasonable Efforts. Each Party shall use Commercially Reasonable Efforts to conduct all activities and responsibilities assigned to it under the Development Plan and to cooperate with and provide reasonable support to the other Party in such other Party's conduct of activities under such plan.

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3.3.2. Allocation of Responsibilities. The Development Plan shall allocate responsibility between the Parties for each of the activities described herein in accordance with Section 3.2.3. CDS and Alimera shall each expend resources in the performance of the development activities in accordance with the Development Plan. For the avoidance of doubt, neither Party shall have any right or obligation to undertake any development activity for Products licensed under this Agreement, other than those allocated to it in the Development Plan and included in the Development Budget, except as set forth in Section 6.3.3. In the event that a Party (a) fails to make any payment to a Third Party due to be made by such Non-Performing Party in connection with development activities as set forth in the Development Plan and Development Budget, or (b) fails to perform development activities allocated to it in the Development Plan and included in the Development Budget, that Party shall be called the "Non-Performing Party." In the event that the Non-Performing Party fails to make any payment to a Third Party due to be made by such Non-Performing Party in connection with development activities as set forth in the Development Plan and Development Budget, it shall notify the other Party in writing within ten (10) Business Days after the missed payment due date. The other Party (the "March-In Party") may, in its sole discretion, decide to make any such payment that the Non-Performing Party fails to make. The associated costs paid by the March-In Party shall be Direct Development Costs, and the Non-Performing Party's failure to pay its share of such costs shall be treated as non-payment of Development Payment pursuant to Section 6.3.2. In the event that the Non-Performing Party fails to perform development activities allocated to it in the Development Plan and included in the Development Budget, (1) it shall so notify the other Party, and (2) the other Party may, in its sole discretion, after providing the Non-Performing Party a reasonable opportunity to cure the failure, perform the relevant activities, in which case the associated costs incurred by the other Party shall be Direct Development Costs, and the Non-Performing Party's failure to pay its share of costs shall be treated as non-payment of Development Payment pursuant to Section 6.3.2.

3.4 Primary Contact Persons. As of the Effective Date, CDS has designated [\*] as CDS' primary contact person and Alimera has designated [\*] as Alimera's primary contact person (each, a "Primary Contact Person"). The Primary Contact Persons shall be responsible for the day-to-day interactions between the Parties related to activities pursuant to the Development Plan and oversight of the day-to-day operations of these activities. The Primary Contact Persons shall attempt to resolve any disputes that arise during the course of implementing the Development Plan. If the Primary Contact Persons cannot resolve any such dispute within thirty (30) days (or such longer reasonable period of time as they may agree) after their initial discussion of such issue, the dispute shall be submitted to the JDT and resolved in accordance with Section 2.4. Each Party may change its Primary Contact Person upon written notice to the other Party.

3.5 Availability of Employees. Each Party agrees to make its employees involved in the conduct of the development activities reasonably available upon reasonable advance notice and during business hours at their respective places of employment to consult with the other Party on issues, including, but not limited to, regulatory, scientific, technical and clinical testing issues, arising under the Development Plan and in connection with any request from any regulatory agency.

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3.6 Visit of Facilities. Subject to the provisions of Article 8, each Party shall permit the other Party or the representatives of the other Party to visit, upon reasonable notice and at reasonably acceptable times, their respective facilities where the development activities are being conducted, and to consult informally, during such visits and by telephone, facsimile and email, with their respective personnel performing work on the development activities. Any information obtained by a Party during such visits shall be treated as Confidential Information in accordance with Article 8 of this Agreement. Each Party shall use Commercially Reasonable Efforts to obtain comparable inspection rights with respect to subcontractors.

3.7 Subcontracts. Subject to the provisions of Article 8 and Section 7.3 hereof, each Party may subcontract portions of the development activities to be performed by it to subcontractors so long as either (a) the JDT has authorized the subcontract and subcontractor (which subcontract shall be consistent with an approved Development Budget), or (b) such Party has obtained the prior written consent of the other Party, which consent shall not be unreasonably delayed or withheld (each such subcontractor, a "Permitted Subcontractor"). In addition to obtaining prior written authorization or consent as required by the foregoing, if the JDT adopts a standard form of subcontract, the Parties shall use Commercially Reasonable Efforts to utilize such standard form of subcontract agreement, as may be modified by the JDT from time to time. In any event, any subcontract entered into pursuant to this Section 3.7, including any standard form of subcontract, shall be consistent with the terms of this Agreement, including providing for intellectual property ownership as set forth herein and all confidentiality obligations of the Parties. With respect to any subcontract, the subcontracting Party shall provide the JDT with a copy of the subcontract within thirty (30) days of execution of such subcontract.

3.8 Information Sharing. Each Party shall provide the other Party or the JDT with such information related to the Development Plan as the other Party may reasonably request.

3.9 Records. The Parties will make available and disclose to one another all results of the work conducted pursuant to the Development Plan and shall keep such records as described in this Section 3.9 or elsewhere in this Agreement; provided, however, that each Party shall maintain in confidence, and shall limit its use of, such results and records in confidence in accordance with Article 8 hereof and shall not use such results or records without written consent of the other Party except to the extent provided in Section 5.9 or other provisions of this Agreement. The Parties shall maintain records of the results in sufficient detail and in good scientific manner appropriate for patent purposes and FDA filings and as will properly reflect all work done and results achieved in the performance of the development activities pursuant to the Development Plan (including, but not limited to, all data in the form required to be maintained under any applicable governmental regulations). Such records shall include books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof, computer information storage means, samples of materials and other graphic or written data generated in connection with the development activities pursuant to Development Plan. Each Party hereby grants the other Party the right to inspect and copy such records upon reasonable advance notice by the other Party for purposes of this Agreement.

3.10 Manufacturing for Clinical Supply Requirements. CDS and/or its Permitted Subcontractors shall use Commercially Reasonable Efforts to provide an adequate and timely

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supply to satisfy Clinical Supply Requirements, in such quantities and of such type and specification as set forth in the Development Plan and all in accordance with GMP and/or ISO standards, to the extent applicable for clinical trials in the relevant country, and other applicable laws and regulations. The Manufacturing Costs for such supply shall be Direct Development Costs.

3.11 Technology Transfer by CDS. Upon the earlier of: (i) the determination by the JDT and (ii) [\*] prior to [\*], CDS and/or its Permitted Subcontractors shall be responsible for providing to Alimera all information, support and materials reasonably necessary to enable Alimera and/or its subcontractors to manufacture and perform quality testing on the Product to satisfy Commercial Supply Requirements, all in accordance with the Development Plan. CDS and/or its Permitted Subcontractors shall be responsible for the following activities in accordance with the Development Plan: (a) oversee and manage technology transfer to commercial manufacture site, (b) oversee and manage manufacturing scale-up and validation activities, (c) transfer analytical methods to commercial manufacture site for stability monitoring, and (d) procure and oversee stability data necessary for IND and NDA filings. Alimera shall have primary responsibility, with reasonable input and assistance from CDS, for the preparation of the Chemistry, Manufacturing and Controls (the "CMC") section of Alimera's IND and NDA filings. Technology transfer shall be effected in accordance with GMP and ISO guidelines, to the extent applicable for Commercialization in the relevant country.

## ARTICLE 4 COMMERCIALIZATION

4.1 Commercialization of Product(s) in the Collaboration Field. Alimera is granted a license under this Agreement to market, distribute and/or sell any Product in the Collaboration Field in the Territory, including, but not limited to, the right to conduct marketing, reimbursement (e.g., seeking and maintaining pricing and reimbursement approvals from Third Party payors), sales and distribution activities. Alimera may subcontract with any Affiliate or Third Party to perform any of the foregoing activities in accordance with Section 5.3.

4.2 Commercialization Budget. Alimera shall have sole responsibility for implementing Commercialization based on Alimera's commercially reasonable expectations of the resources and expenses required to Commercialize each Product in the Territory, taking into account industry standards and the competitive environment in effect from time to time with regard to each Product. Alimera shall prepare a budget ("Commercialization Budget") and consider in good faith incorporating into the Commercialization Budget any comments made by CDS prior to finalizing such budget. The Commercialization Budget shall set forth, on a rolling two (2) year basis, the projected sales and the projected Direct Commercialization Costs broken down on a calendar quarter-by-quarter and Product-by-Product basis. Alimera shall prepare semi-annual updates to the Commercialization Budget prior to June 30 and December 31 of each year in which Alimera has a Commercialization Budget or engages in Commercialization of any Products, and shall provide CDS with copies of such semi-annual updates. Prior to finalizing the initial Commercialization Budget and prior to finalizing each subsequent semi-annual updated Commercialization Budget, Alimera shall arrange for the Parties to have an in-person meeting (or, at CDS' option, a meeting by telephone, videoconference or other means), during which an executive from Alimera shall present in reasonable detail its planned Commercialization

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activities and Commercialization Budget for the time period covered in the subject Commercialization Budget and CDS shall have opportunities to ask questions and to present its comments on the applicable Commercialization Budget. It is understood and agreed that [\*] shall have the right and ability to [\*]. Alimera shall provide an initial draft Commercialization Budget to CDS for its review as soon as it is available, but in no event later than the earlier of (a) [\*] prior to [\*] or (b) [\*] prior to incurring Direct Commercialization Costs estimated to be in excess of [\*] in the aggregate.

4.3 Diligence. Alimera shall use Commercially Reasonable Efforts to Commercialize each Product in [\*] (collectively, the "Major Markets") and in all countries outside the Major Markets, except for any country outside the Major Markets as to which Alimera has made an election pursuant to Section 4.3.9. For purposes of this Section 4.3 (including Subsections 4.3.1- 4.3.9), the term "Alimera" shall include Alimera and any of its Affiliates, sublicensees and subcontractors. Without limiting the foregoing, Alimera agrees to the following specific obligations:

4.3.1. Alimera shall effect a First Commercial Sale in the United States of the first Product to receive Approval in the United States (the "Alimera First Product") no later than [\*] after obtaining such Approval. Alimera's nonperformance of an obligation in this Section 4.3.1 shall be excused to the extent directly attributable to a disruption in Commercial Supply Requirements, but only to the extent that such disruption and the impact thereof is outside the control of Alimera.

4.3.2. With respect to Commercialization of the Alimera First Product, Alimera shall expend not less than [\*] in Direct Commercialization Costs (excluding Manufacturing Costs) on or before [\*], provided that if Alimera is making Commercialization expenditures substantially in accordance with a Commercialization Budget designed to provide for such level of expenditures and the FDA provides Approval sooner than reasonably contemplated by the Commercialization Budget, then the failure to spend at least [\*] in Direct Commercialization Costs (excluding Manufacturing Costs) on or before [\*] shall be excused.

4.3.3. With respect to Commercialization of the Alimera First Product, Alimera shall expend not less than [\*] in Direct Commercialization Costs (excluding Manufacturing Costs, but including expenditures referred to in Section 4.3.2) on or before [\*].

4.3.4. With respect to Commercialization of the Alimera First Product, Alimera shall expend not less than [\*] in Direct Commercialization Costs (excluding Manufacturing Costs) between [\*] and [\*].

4.3.5. Alimera shall cause Gross Sales of Products in the United States during the [\*] period referred to in Section 4.3.4 to be at least [\*] more than Gross Sales of Products in the United States during the immediately preceding [\*] period. Alimera's

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nonperformance of an obligation in this Section 4.3.5 shall be excused to the extent directly attributable to (1) one or more of the following events, but only to the extent that such event is outside the control of Alimera: a breach of this Agreement by CDS, a disruption in Commercial Supply Requirements, or a Product Recall, or (2) one or more of the following events, but only to the extent that such event materially and adversely affects the market for the first Product: FDA action or regulatory guidance affecting Product, a change in reimbursement rates or policies relating to Product, or the introduction of one or more competitive products or services that provide for superior dosing, safety or efficacy.

4.3.6. If Alimera fails to meet any spending obligation set forth in Sections 4.3.2, 4.3.3 or 4.3.4 and such nonperformance is not excused, Alimera may cure such failure by paying to CDS an amount equal to [\*]. Alimera's right to cure under this Section 4.3.6 shall terminate upon a Change of Control of Alimera.

4.3.7. If Alimera fails to achieve the Gross Sales obligation set forth in Section 4.3.5, Alimera may cure such failure by paying to CDS an amount equal to [\*] (the "Extrapolated Net Profits"). For purposes of this Section 4.3.7, the Extrapolated Net Profits for the [\*] period referred to in Section 4.3.4 shall be determined by the following formula: [\*]. Alimera's right to cure under this Section 4.3.7 shall terminate upon a Change of Control of Alimera.

4.3.8. If Alimera fails to meet any of its obligations under subsections 4.3.1 - 4.3.5 and does not cure such failure in accordance with this Agreement within thirty (30) days of receiving a written notice from CDS requesting Alimera to cure such failure, then CDS may choose one of the following two options: (a) terminate this Agreement, or (b) terminate this Agreement only with respect to the Alimera First Product. In the event of termination pursuant to this Section 4.3.8, Alimera shall not, for a period of [\*] from the date of such termination, Develop or Commercialize, or license or otherwise assist an Affiliate or a Third Party to Develop or Commercialize, any product that is Approved or designed to be Approved (1) to [\*] or (2) to deliver a  $[\ensuremath{^*}]\xspace$  . For purposes of this Section 4.3.8, the term "Develop" shall mean performance of human clinical trials for a product. In the event of termination of this Agreement with respect to the Alimera First Product, CDS shall no longer be bound by Section 5.1.2(1), (2), (3) or (4) with respect to such Product. After termination pursuant to this Section 4.3.8 and in the event that CDS (i) makes a First Commercial Sale of the Alimera First Product in the United States and (ii) reaches the CDS Profitability Date for the Alimera First Product, CDS shall thereafter pay Alimera [\*] of CDS Net Income realized by CDS in the United States with respect to such Product until such time as the sum of all such payments plus the revenues otherwise realized by Alimera with respect to such

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Product in the United States equal the amount of Direct Development Costs and Direct Commercialization Costs previously incurred, on a cash basis, or reimbursed by Alimera with respect to such Product in the United States; provided, however, that in the event that there are CDS Net Losses in any calendar quarter after the CDS Profitability Date, any payment to Alimera shall be offset by such CDS Net Losses.

4.3.9. For clarification, Alimera may elect not to engage in Commercialization in any country outside the Major Markets. If Alimera determines not to engage in Commercialization of any Product in any country outside the Major Markets, Alimera shall so notify CDS. At any time after receipt of such notice, CDS may by written notice to Alimera, effective upon the giving of such notice, terminate Alimera's license(s), and rights to Commercialize, in such country. Thereafter CDS may, in its sole discretion, directly or through an Affiliate or Third Party, Commercialize the relevant Product(s) in such country. In the event of such termination with respect to a country, CDS shall no longer be bound by Section 5.1.2(1), (2), (3) or (4) with respect to such country.

4.4 Costs of Commercialization. Regardless of the Profitability Date for a Product, Alimera shall have sole responsibility for paying all costs and expenses incurred in connection with Commercializing such Product in the Collaboration Field in the Territory, including, but not limited to, Direct Commercialization Costs; with the exception that CDS shall be responsible for paying: (a) the CDS Patent Costs paid after the first Product Profitability Date, subject to Section 7.1.2, (b) all UKRF Costs and (c) insurance premiums paid by CDS to maintain insurance required by Section 10.4 to the extent such insurance relates to Product (i.e., if insurance covers risks other than risks related to Commercialization of Products, then only an appropriate portion of such premiums shall be reimbursed). Alimera shall reimburse CDS for [\*] of the amount described in clauses (a), (b) and (c) of the preceding sentence within thirty (30) days after the date of invoice from CDS; provided, however, that the amount of the [\*] that Alimera reimburses CDS in any calendar year shall not exceed [\*]. The costs set forth in (a), (b) and (c) of this Section 4.4 for which Alimera has a reimbursement responsibility shall be collectively referred to herein as the "CDS Commercialization Costs". In the event that Alimera fails to reimburse CDS within the time period specified above, any future payment to CDS shall be increased by an amount that is calculated as follows: the amount of the non-reimbursed CDS Commercialization Costs is multiplied by  $[\,^\star]\,,$  and that amount is compounded annually at the compounding rate of [\*] per annum, for any period in which any portion of such costs remains non-reimbursed. Alimera may pay all or any portion of the unpaid CDS Commercialization Costs plus any interest accrued and due at any time. Notwithstanding the foregoing, CDS may exercise its rights pursuant to Section 11.2 of this Agreement.

4.5 Manufacturing for Commercial Supply Requirements. Alimera shall use Commercially Reasonable Efforts to provide an adequate and timely supply to satisfy Commercial Supply Requirements. Subject to the terms of this Agreement, Alimera shall have the right to manufacture, itself or through any Third Party, any Product, under the licenses granted to Alimera pursuant to Article 5 and in accordance with Section 5.3. Alimera shall be responsible for ensuring that all such manufacturing is carried out in accordance with GMP and/or ISO standards to the extent applicable for Commercialization in the relevant country.

4.6 Product Recalls. Alimera shall have the sole right and responsibility and authority to carry out any Product Recall, whether or not such Recall is required or requested by a

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governmental authority. If any governmental authority having jurisdiction requires or reasonably requests Alimera to Recall a Product due to a defect in the manufacture, processing, packaging or labeling of the Product or for any other reason whatsoever, Alimera shall immediately notify CDS. Alimera shall be responsible for carrying out any Recall as expeditiously as possible and in such a way designed to cause the least disruption to the sales of the Product and to preserve the goodwill and reputation attached to the Product and to the names of Alimera and CDS. Alimera agrees to maintain the appropriate records and procedures to permit a Product Recall. All Direct Costs associated with any Product Recall, to the extent such costs are not covered by insurance, shall be Direct Commercialization Costs; provided, however, that in the event that the Product Recall is required due to Alimera's negligence or misconduct (including a manufacturing quality defect in the Product) or any other reason within Alimera's control, all such expenses shall be borne solely by Alimera and, in such event, shall not be Direct Commercialization Costs.

#### ARTICLE 5 GRANT OF RIGHTS

5.1 Grant of License by CDS.

5.1.1. License to First Product. Subject to the terms and conditions of this Agreement, CDS hereby grants to Alimera an exclusive (even as to CDS) right and license under CDS' interest (i.e. subject to the UKRF Licenses) in the CDS Technology, solely to make, have made, use, offer to sell, sell, and import First Product in the Collaboration Field in the Territory.

5.1.2. License to Products Other Than First Product. Subject to the terms and conditions of this Agreement and the B&L Agreement (wherein CDS  $% \left[ {{\left[ {{{\rm{CDS}}} \right]}_{\rm{T}}}} \right]$ granted certain rights to the CDS Technology), CDS hereby grants to Alimera a non-exclusive right and license under CDS' interest (i.e. subject to the UKRF Licenses) in the CDS Technology, solely to make, have made, use, offer to sell, sell, and import Products other than First Product in the Collaboration Field in the Territory, provided that during the Term of this Agreement, and subject to the terms and conditions of this Agreement and the B&L Agreement, (1) CDS shall not grant a license to any Affiliate or Third Party under CDS' interest in the CDS Technology to make, have made, use, offer to sell, sell, or import Products in the Collaboration Field in the Territory, (2) CDS shall not itself use the CDS Technology to make, have made, use, offer to sell, sell, or import Products in the Collaboration Field in the Territory, (3) CDS shall not grant a license to any Affiliate or Third Party under CDS' interest in the CDS Technology to make, have made, use, offer to sell, sell, or import in the Collaboration Field in the Territory any product that otherwise meets the definition of Product under Section 1.77 except that such product is Approved or designed to be Approved to deliver  $\left[ \star \right]$  and (4) CDS shall not itself use the CDS Technology to make, have made, use, offer to sell, sell, or import in the Collaboration Field in the Territory any product that otherwise meets the definition of Product under Section 1.77 except that such product is Approved or designed to be Approved to deliver [\*]

5.1.3 License to Exhibit 1.11B Patents. Subject to the terms and conditions of this Agreement and only to the extent permitted by the B&L Agreement, CDS hereby grants to

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Alimera a non-exclusive right and license under any interest CDS may have from time to time in the United States and foreign patents and patent applications listed in Exhibit 1.11B, solely to make, have made, use, offer to sell, sell, and import Products in the Collaboration Field in the Territory, except for products that would fall under the definition of Licensed Products in the B&L Agreement.

5.2 Grant of License by Alimera. Subject to the terms of this Agreement, Alimera hereby grants to CDS a right and license under Alimera's interest in the Alimera Know-How as necessary for CDS to perform its obligations under this Agreement, including, but not limited to, its obligations under the Development Plan.

5.3 Sublicenses and Subcontracts. Subject to the terms and conditions of this Agreement, Alimera may grant sublicenses and subcontracts to its Affiliates or to Third Parties to perform Commercialization activities for Products under the licenses granted pursuant to Sections 5.1.1 and 5.1.2 of this Agreement, provided that for sublicenses and subcontracts under which (1) some or all of Alimera's rights to a Product, including, but not limited to, marketing rights and/or distributing rights, are sold, licensed or otherwise transferred and/or (2) consideration owed by Alimera exceeds [\*] Alimera shall obtain CDS' prior written consent, which consent shall not be unreasonably withheld or delayed. In the event of a proposed sublicense or subcontract that requires CDS' prior written consent as described in the foregoing, Alimera shall present CDS with a summary of the principal terms of the proposed transaction, including the identity of the proposed subcontractor or sublicensee. CDS shall promptly consent or provide justification for its objection and negotiate in good faith with Alimera regarding terms that would be satisfactory. Each sublicense or subcontract shall be consistent with the terms and conditions of this Agreement, shall be at arm's length and shall include such terms as are necessary to permit Alimera to fulfill its obligations hereunder. Alimera shall be responsible for the operations of any sublicensee or subcontractor relative to this Agreement as if such operations were carried out by Alimera itself, including, but not limited to, any payment provided for hereunder, regardless of whether the terms of any sublicense or subcontract provide for such payment to be paid by the sublicensee or subcontractor directly to CDS. Alimera shall provide CDS with a copy of each such sublicense or subcontract promptly after its execution; provided, however, that Alimera may redact such copies in order to protect the confidential information of the Third Party. The terms of any sublicense or subcontract, or proposed sublicense or subcontract, shall be deemed to be Confidential Information of Alimera. CDS acknowledges that Alimera intends to grant a sublicense of rights to one or more Third Parties for the development and Commercialization of Product in [\*]. For avoidance of doubt, CDS' acknowledgement in the preceding sentence shall not constitute CDS' consent, which is required before Alimera enters into such a sublicense pursuant to this Section 5.3. Each sublicensee or subcontractor and its employees, contractors, consultants, clinical investigators and agents shall be required to assign all Improvements to Alimera pursuant to Section 7.3.

5.4 Ownership of and Rights to Inventions. Except as otherwise provided under this Agreement, ownership of all Inventions made by either Party shall be governed by applicable United States patent law. Alimera hereby assigns and agrees to assign to CDS a co-ownership interest in Alimera's interest in any Alimera Improvements, excluding any rights to any trademarks. Subject to Section 5.5, each Party shall have worldwide rights to use, practice and

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sublicense any such Alimera Improvements, without any accounting to, reporting to, or other obligation to, or consent from, the other Party. If a Party licenses or otherwise transfers to a Third Party any Alimera Improvements, the other Party shall cooperate and give such consent to such Party to enter into such license or transfer as may be required to permit such Party to license or transfer the Alimera Improvements to the Third Party without a duty to account to such other Party.

5.5 Limitation on Use. Notwithstanding any other provisions of this Agreement, neither Alimera nor any of its Affiliates, subcontractors or sublicensees shall use Alimera Improvements for any product that falls within the definition of CDS Core Technology, except for (1) Products (other than any Product(s) for which Alimera's license(s) have been terminated pursuant to Sections 4.3.8, 4.3.9 or 11.5 of this Agreement) during the Term of this Agreement, (2) any Product(s) for which CDS has granted a license to Alimera pursuant to Section 11.5.1, during the term of such license, and (3) Option Products for which CDS has granted a license to Alimera pursuant to Section 5.8.2, during the term of such license. Alimera shall ensure that any agreement it enters into with a licensee, sublicensee, acquirer, acquiree, transferee or merger or consolidation partner of or with Alimera, or acquirer or transferee of substantially all of the assets or stock of Alimera, or of the assets or business relating to this Agreement or the Alimera Improvements, includes the same limitation of use as set forth in this Section 5.5, and any such party shall be bound by such limitation.

#### 5.6 Reservation of Rights.

5.6.1. Reservation of Rights by CDS. All rights and interests not expressly granted to Alimera are reserved by CDS (the "Reserved Interests") for itself, its Affiliates and partners (other than Alimera) and other licensees and sublicensees, including, but not limited to, the rights to use and grant licenses under the CDS Technology or any other technology owned or controlled by CDS to make, have made, use, offer to sell, sell, have sold and import products (other than Products for so long as Alimera has a license to such Products under this Agreement). It shall not be a breach of this Agreement for CDS, acting directly or indirectly, to exploit its Reserved Interests in any manner anywhere in the Territory, whether or not such activity is competitive with the activities of Alimera, including, but not limited to, the research, development and Commercialization or licensing of others to research, develop and Commercialize products (other than Products for so long as Alimera has a license to such Products under this Agreement). Except as otherwise expressly provided in this Agreement, for the avoidance of doubt, CDS shall be free to enter into an agreement with any Third Party or Third Parties under the CDS Technology or any other technology owned or controlled by CDS or its Affiliate or a Third Party, to research, develop and Commercialize any and all products (other than Products for so long as Alimera has a license to such Products under this Agreement), including, but not limited to, products that potentially compete in the same indication or product market as a Product, and products that use or include any or all compounds that are not, at the time of such agreement, the subject of a license granted pursuant to Section 5.8.3.

5.6.2. Reservation of Rights by Alimera. Except as otherwise expressly provided in this Agreement, for the avoidance of doubt, Alimera shall be free to enter into an agreement with any Third Party or Third Parties under the Alimera Know-How, the Alimera-Prosecuted Patent Rights or any other technology owned or controlled by Alimera or its Affiliate or a Third

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Party, to research, develop and Commercialize any and all products, including, but not limited to, products that potentially compete in the same indication or product market as a Product.

5.7 No Grant of Other Technology or Patent Rights. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party hereto, as a result of this Agreement, obtain any ownership interest or license in or other right to any technology, Know-How, patents, patent applications, products, or biological materials of the other Party, including, but not limited to, items owned, Controlled or developed by the other Party, at any time pursuant to this Agreement. This Agreement does not create, and shall under no circumstances be construed or interpreted as creating, an obligation on the part of either Party to grant any license to the other Party other than as expressly set forth herein. Any further contract or license agreement between the Parties shall be in writing.

5.8 Options to Licenses in the Collaboration Field.

5.8.1. Options. Subject to the terms and conditions of this Agreement and the B&L Agreement, CDS hereby grants to Alimera three (3) options to obtain a non-exclusive right and license under CDS' interest (i.e. subject to the UKRF Licenses) in the CDS Technology, solely to make, have made, use, offer to sell, sell and import an Option Product in the Collaboration Field (each option relating to a particular compound is referred to herein as an "Alimera Compound Option," and the three (3) options are collectively referred to herein as the "Alimera Compound Options"). Each license granted in connection with an Alimera Compound Option will provide that during the term of such license, and subject to the B&L Agreement, CDS shall not (a) grant a license to any Affiliate or Third Party under CDS' interest in the CDS Technology to make, have made, use, offer to sell, sell, or import such Option Product in the Collaboration Field in the Territory, and (b) itself use the CDS Technology to make, have made, use, offer to sell, sell, or import such Option Product in the Collaboration Field in the Territory during the term of such license.

5.8.2. Exercise of Options. Alimera may exercise, in accordance with this Section 5.8, an Alimera Compound Option at any time during the Option Term, by submitting a written request to CDS indicating its intent to exercise such option and specifying the specific compound as to which it wishes to exercise the option. CDS shall have [\*] Business Days, after it receives such notice, in which to notify Alimera in the event that CDS, acting in good faith, has already entered into an agreement or term sheet with a Third Party that includes the specific compound specified by Alimera. In that event, Alimera may not exercise the Alimera Compound Option with respect to that specific compound; provided, however, that if CDS and such Third Party fail to consummate a license or other agreement relating to such compound or such agreement is terminated during the Option Term, CDS shall promptly notify Alimera that such compound is no longer subject to any Third Party rights and Alimera may exercise the Alimera Compound Option with respect to such compound in accordance with this Section 5.8.2. If CDS has not notified Alimera within the time period set forth above, then Alimera shall be permitted to exercise the Alimera Compound Option with regard to that specific compound.

5.8.3. Grant of License. Upon the exercise of any Alimera Compound Option under Section 5.8.2, CDS may choose one of the following two options: (a) the Parties will enter into a collaboration agreement (the "Option Collaboration Agreement") to develop and

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Commercialize the Option Product on the same terms as this Agreement (including, but not limited to, the same economic terms, including license fee, milestone payment and profit split) and Alimera shall reimburse CDS for [\*] of all costs and expenses CDS incurred (excluding any CDS Patent Costs related to Existing CDS Patent Rights or costs that are Development Costs or otherwise reimbursed by Alimera under this Agreement) with respect to the Option Compound and the Option Product from the Effective Date of this Agreement until the effective date of the Option Collaboration Agreement; or (b) CDS shall grant Alimera a license under the CDS Technology, as then in effect, to make, have made, use, offer to sell, sell and import the Option Product in the Collaboration Field in the Territory, under the following terms: (A) CDS shall receive a royalty of [\*] of Net Sales of the Option Product in the Territory, and (B) Alimera shall reimburse CDS [\*] with respect to the Option Compound and the Option Product from the Effective Date of this Agreement until the effective date of such license, and (C) such other non-financial terms and conditions as set forth on Exhibit 5.8.3 and other customary terms and conditions. If the Parties have not entered into an agreement under (a) or (b), as CDS chooses, within [\*] Business Days after Alimera exercises an Alimera Compound Option, then the matter shall be referred to dispute resolution in accordance with Section 12.7 hereof, and the terms of such agreement shall be consistent with those specified above in (a) or (b), as applicable.

5.8.4. Reservation of Rights by CDS. The existence of the Alimera Compound Options under Section 5.8.1 shall not limit the reservation of rights by CDS pursuant to Section 5.6, and CDS shall have no obligation to refrain from including any or all compounds in a license with a Third Party or Third Parties, except to the extent of any license that is actually granted to Alimera pursuant to Section 5.8.3 or to the extent restricted by Sections 5.1.1 and 5.1.2, from and after the date of such license. In the event that CDS grants Alimera a license to one or more Option Products pursuant to Section 5.8.3, the reservation of rights by CDS will remain the same as set forth in Section 5.6.1, except that the phrase "Products and Option Products for which CDS has granted a license to Alimera" shall be substituted in place of "Products" wherever it is used in Section 5.6.1 during the term of any such license.

5.9 Clinical IP.

5.9.1. Right of Access to Clinical IP. Alimera and CDS shall jointly own all Clinical IP and shall provide each other with a Right of Access to Clinical IP. Each Party may exercise this right of access for itself, its Affiliates and any licensees, sublicensees or any other Third Party without the consent of the other Party.

5.9.2. Cooperation. Each Party shall use Commercially Reasonable Efforts, and shall reasonably cooperate with the other Party, to provide the other Party with such waivers, irrevocable cross reference letters, assignments, and/or other reasonable documentation as may be necessary or useful for the other Party's full exercise of any Right of Access to Clinical IP granted pursuant to this Section 5.9.

5.10 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are rights to "intellectual property" as defined in Section 101(35A) of the Bankruptcy Code. CDS acknowledges and agrees that in connection

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with such rights and licenses Alimera is hereby granted a right of access and a right to obtain possession of and to benefit from (i) copies of research data, (ii) laboratory samples, (iii) product samples and inventory, (iv) formulas, (v) laboratory notes and notebooks, (vi) data and results related to clinical trials, (vii) copies of regulatory filings and Approvals, (viii) rights of reference in respect of regulatory filings and Approvals, (ix) preclinical research data and results, and (x) marketing, advertising and promotional materials, all of which constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code and (xi) all other embodiments of such intellectual property, whether any of the foregoing are in CDS' possession or control or in the possession and control of Alimera or Third Parties. CDS agrees not to interfere with Alimera's exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement.

ARTICLE 6 COSTS & REVENUES - PRE AND POST PROFITABILITY DATE

6.1 License Fee. If this Agreement is not terminated pursuant to Section 11.4, then the [\*] in principal plus all accrued interest due under the Earnest Money Loan shall thereafter be treated as paid in full as the payment of a license fee, and the security interest under the Security Agreement (the "Security Agreement") made by CDS in favor of Alimera and effective as of October 19, 2004, as amended on November 18, 2004, shall terminate, and Alimera shall execute and deliver to CDS such documents as CDS may reasonably request to evidence such terminated pursuant to Section 4 of the Security Agreement. If this Agreement is terminated pursuant to Section 11.4, then the Security Agreement and the promissory notes issued in respect of the Earnest Money Loan shall remain in full force and effect.

6.2 Milestone Payment. Alimera shall make an additional payment of [\*] ("Milestone Payment") to CDS upon [\*]. For purposes of this Section 6.2, the Parties agree that [\*].

6.3 Direct Development Costs. Each Party shall pay [\*] of the total Direct Development Costs of a Product incurred in accordance with the Development Budget.

6.3.1. Monthly Reporting, Sharing and Reconciling of Direct Development Costs. During the course of implementing the Development Plan, within fifteen (15) calendar days after the end of each calendar month, each Party shall report in writing to the other Party a detailed itemization (including copies of any third party invoices) of the actual Direct Development Costs incurred, on a cash basis, by each Party in the preceding calendar month. The Parties shall reconcile amounts owed for actual Direct Development Costs on a monthly basis as follows: to the extent (i) a Party incurred, on a cash basis, Direct Development Costs in a calendar month that are within (and do not exceed) the costs allocated to be incurred by that Party in the Development Budget and (ii) the amounts in (i) exceed the Direct Development Costs incurred, on a cash basis, by the other Party in that calendar month that are within (and do not exceed) the costs allocated to be incurred, on a cash basis, by the other Party in the Development Budget, the Party that paid the greater amount of budgeted Direct Development Costs shall issue an invoice to the other Party for [\*] of the excess and the other Party shall pay

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to the invoicing Party the amount of such invoice (the "Development Payment") within thirty (30) calendar days after delivery of the invoice.

6.3.2. Non-Payment. In the event that a Party (the "Non-Paying Party") fails to make timely payment to the other Party (the "Owed Party") for all or a portion of its Development Payment for a Product pursuant to Section 6.3, then any distribution of Net Profits and the Milestone Payment to CDS shall be adjusted by an amount that is calculated as follows: the amount of the unpaid Development Payment is multiplied by [\*], and that amount is compounded annually at the compounding rate of [\*] per annum (the total amount is called the "Compounded Development Payment"), for any period in which any portion of the Compounded Development Payment remains outstanding. Specifically, if Alimera is the Owed Party, then any Net Profits Payment and the Milestone Payment to CDS shall be reduced by the Compounded Development Payment due from CDS to Alimera until the amount of such Net Profits Payment and the Milestone Payment to CDS is [\*] and any remaining balance of the Compounded Development Payments that CDS owes to Alimera shall be carried forward until the amount of such Compounded Development Payments are paid off. If CDS is the Owed Party, then any Net Profits Payment to CDS shall be increased by the Compounded Development Payment due from Alimera to CDS up to [\*] of Alimera's share of Net Profits and any remaining balance of the Compounded Development Payments that Alimera owes to CDS shall be carried forward and offset against Alimera's share of Net Profits in subsequent periods until such Compounded Development Payments are paid off. All or any portion of the unpaid Compounded Development Payment may be paid at any time for such Product. Notwithstanding the foregoing, the Owed Party may exercise its rights pursuant to Section 11.3 or 11.5 of this Agreement.

6.3.3. Dispute over Direct Development Costs. Pursuant to the process described in Section 3.2.2, in the event that the JDT and/or the Parties cannot reach an agreement over direct development costs proposed by a Party to implement the Development Plan, the issue shall be referred to the senior management of the Parties in accordance with Section 12.7.1. In the event that the senior management of the Parties cannot reach an agreement over such proposed costs (the "Disputed Costs"), such dispute may be resolved through arbitration in accordance with Section 12.7.2. In the meantime, while the matter is in arbitration, the Party that proposed the Disputed Costs may, in its sole discretion, incur such costs, in addition to those allocated to such Party in the Development Budget, and the Parties otherwise would proceed in accordance with the then existing Development Plan and Development Budget until the matter is resolved.

(a) If the Disputed Costs, or any portion thereof, are determined through arbitration in accordance with Section 12.7.2 to be Direct Development Costs that are reasonably necessary to develop the Product and the proposing Party has paid such costs in accordance with the preceding sentence (the "Determined Disputed Costs"), then the non-proposing Party shall pay to the proposing Party an amount that is calculated as follows: an amount that corresponds to [\*] of the Determined Disputed Costs is multiplied by [\*] and that amount is compounded annually at the compounding rate of [\*] per annum (the total amount is called the "Compounded Disputed Costs"), for the period commencing on the date the determination is made by the dispute resolution procedure for so long as any portion of the Compounded Disputed Costs remain outstanding. In the event that the non-proposing Party fails

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to pay the Compounded Disputed Costs, any distribution of Net Profits and the Milestone Payment for that Product to CDS shall be adjusted by the Compounded Disputed Costs according to the following: (i) if CDS owes Compounded Disputed Costs to Alimera, then any Net Profits Payment and Milestone Payment to CDS shall be reduced by the Compounded Disputed Costs due from CDS to Alimera until the amount of such Net Profits Payment to CDS is [\*] and any remaining balance of the Compounded Disputed Costs that CDS owes to Alimera shall be carried forward until such Compounded Disputed Costs are paid off, or (ii) If Alimera owes Compounded Disputed Costs to CDS, then any Net Profits Payment to CDS shall be increased by the Compounded Disputed Costs due from Alimera to CDS up to [\*] of Alimera's share of Net Profits and any remaining balance of the Compounded Disputed Costs that Alimera owes to CDS shall be carried forward and offset against Alimera's share of Net Profits in subsequent periods until such Compounded Disputed Costs are paid off. All or any portion of the unpaid Compounded Disputed Costs may be paid at any time for such Product. Notwithstanding the foregoing, the Owed Party may exercise its rights pursuant to Section 11.3 or 11.5 of this Agreement.

(b) If the Disputed Costs are determined pursuant to Section 2.4 or through the dispute resolution procedure in accordance with Section 12.7 not to be Direct Development Costs that are reasonably necessary to develop the Product, and the proposing Party has paid such costs, then the proposing Party shall bear the Disputed Costs and the non-proposing Party shall have no obligation to pay.

6.4 Revenues Prior to Profitability Date. Prior to the Profitability Date for each Product, Alimera shall retain all Gross Sales generated from such Product in the Collaboration Field in the Territory.

6.5 Costs and Revenues After the Profitability Date.

6.5.1. Net Profits. From and after the Profitability Date for each Product and subject to (b) below, each Party shall be entitled to [\*] of Net Profits for that Product, calculated on a calendar quarter-by-quarter and country-by-country basis. Such Net Profits Payment to CDS shall be deemed royalty for licenses granted by CDS to Alimera under Article 5, provided that Alimera has a right to recoup from such royalty to CDS any Compounded Development Payment and Compounded Disputed Costs that CDS owes Alimera pursuant to Sections 6.3.2 and 6.3.3 as pre-payments of such royalty.

(a) Reporting; Reconciliation of Net Profits. After the incurrence of Commercialization costs by Alimera, Alimera shall be responsible for issuing a written report to CDS within [\*] calendar days (or as the Parties may otherwise agree) after the end of each calendar quarter, which such report shall include the following calculations:

> (i) Direct Commercialization Costs incurred, on a cash basis, by Alimera for each Product in the preceding calendar quarter and, in the event that there are Net Profits in such preceding calendar quarter, Direct Commercialization Costs incurred in prior quarters to the extent such costs are taken into account in calculating Net Losses that are offset from such Net Profits pursuant to Section 6.5.1 (b);

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(ii) the quantity of each Product sold in the preceding calendar quarter;

(iii) for each calendar quarter with Net Losses, the calculation of Gross Sales, Net Sales and Net Losses;

(iv) for each calendar quarter with Net Profits, the calculation of Gross Sales, Net Sales, Net Profits; and in the event that Net Profits are offset by Net Losses previously realized pursuant to Section 6.5.1(b), such Net Losses; and

(v) the amount of Net Profits, if any, to which each Party is entitled for such calendar quarter.

All of the reports and payments in this Section 6.5 shall be made in U.S. dollars. If any currency conversion is required in connection with the calculation of Gross Sales, Net Sales and Net Profits hereunder, such conversion shall be made in accordance with GAAP.

(b) Net Profits Payment. Alimera shall pay to CDS the amount of Net Profits to which CDS is entitled for such calendar quarter within [\*] calendar days after the end of such calendar quarter (the "Net Profits Payment"); provided that Alimera may offset [\*] of the Net Losses previously realized by Alimera (plus interest as described below, if applicable) on a Product-by-Product and country-by-country basis up to a maximum offset of [\*] of the amount of Net Profits Payment to which CDS is otherwise entitled for such calendar quarter until [\*] of such Net Losses previously realized by Alimera (plus interest as described below if applicable) are offset. In the event that Alimera incurs Net Losses, Alimera shall be entitled to recover under the preceding offset an amount equal to [\*] of the amount of the Net Losses previously realized by Alimera plus interest, compounded annually at the compounding rate of [\*] per annum from the time that such Net Losses are incurred until the time such Net Losses (plus interest), or portion thereof, have been offset pursuant to this paragraph. [\*] Notwithstanding the foregoing, CDS may, at any time, elect to permit Alimera to retain [\*] of Net Profits until [\*] of the Net Losses previously realized by Alimera have been offset. If CDS makes such an election, then no interest charge shall accrue with respect to the Net Losses between the time CDS makes such election and the time they are recovered by Alimera by operation of the offset. In the event that, during any calendar quarter, Alimera makes Commercial sales of two Products that are otherwise identical except that they are Approved for two different indications (the first Product for which Alimera has made Commercial sales shall be called "Product 1" and the second Product for which Alimera has made Commercial sales shall be called "Product 2"), so that it is not reasonably possible to allocate Net Sales attributable to each such Product, then Net Profits and Net Losses for such Products shall be determined as follows for periods in which there are Commercial sales of both Product 1 and Product 2:

The "Product 2 Profitability Date" shall be deemed to be the first day of the first calendar quarter (i) that begins at least [\*] after [\*] and (ii) in

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which the aggregate of Net Sales of Product 1 and Product 2 exceed the aggregate of Direct Commercialization Costs for Product 1 and Product 2. Before the Product 2 Profitability Date, Net Profits for Product 1 shall be the aggregate of Net Sales of Product 1 and Net Sales of Product 2 minus the Direct Commercialization Costs of Product 1, and such Net Profits shall be distributed as provided in the foregoing in this Section 6.5.1(b). After the Product 2 Profitability Date, Net Sales and Direct Commercialization Costs of Product 1 and Product 2 shall be aggregated for the purpose of determining Net Profits and Net Losses for Product 1 and Product 2, such that (i) to the extent the aggregate Net Sales for Product 1 and Product 2 exceeds the Direct Commercialization Costs of Product 1 and Product 2, such amount of difference shall be the aggregate Net Profits for Product 1 and Product 2, and (ii) to the extent the Direct Commercialization Costs of Product 1 and Product 2 exceeds the aggregate Net Sales for Product 1 and Product 2, such amount of difference shall be the aggregate Net Losses for Product 1 and Product 2, provided that all Direct Commercialization Costs incurred by Alimera for Product 2 prior to the Product 2 Profitability Date (plus interest as described above, if applicable), shall be treated as aggregate Net Losses for Product 1 and Product 2; further provided that to the extent it is not possible to separately track Direct Commercialization Costs for Product 1 and Product 2, such Direct Commercialization Costs shall be reasonably allocated between Product 1 and Product 2. The distribution of such aggregate Net Profits and offset of such aggregate Net Losses shall be as provided in the foregoing in this Section 6.5.1(b). In the event that, during any calendar quarter, Alimera makes Commercial sales of three or more Products that are otherwise identical except that they are Approved for three or more different indications so that it is not reasonably possible to allocate Net Sales attributable to each such Product, the Parties agree to work together in good faith to extend the principles reflected in the foregoing method of calculation to include such third or additional Products.

(c) Non-Payment. In the event that Alimera fails to make timely payment to CDS for all or a portion of a Net Profits Payment pursuant to this Section 6.5.1, CDS shall provide written notice to Alimera and Alimera shall have fifteen (15) business days in which to cure the nonpayment. If after such notice, Alimera fails to cure the nonpayment within such fifteen (15) business day period, the portion of the unpaid Net Profits Payment shall increase any future Net Profits Payments to CDS for any future period by an amount that is calculated as follows: the amount of the unpaid Net Profits Payment is multiplied by [\*], and that amount is compounded annually at the rate of [\*] per annum (the total amount is called the "Compounded Net Profits Payment"), for the period in which any portion of the Net Profits Payment remain outstanding. Alimera shall have the right to pay all or any portion of the unpaid Compounded Net Profits Payment plus any interest accrued and due at any time. Notwithstanding the foregoing, CDS may exercise its rights pursuant to Section 11.2 of this Agreement.

(d) Consideration for Net Profits Payments. In consideration of all rights granted, and information provided by CDS to Alimera, and the amount of Direct Development Costs paid by CDS under this Agreement with respect to Product(s), the Parties agree that the amount of Net Profits Payments set forth in Section 6.5 reflects the value of all such rights granted, information provided and costs paid, and such Net Profits Payments shall be paid whether or not such Product is covered by a Valid Claim in the CDS Patent Rights, and whether or not such Net Profits Payments under this Section 6.5 extend beyond the term of any CDS Patent Rights containing Valid Claims covering such Product.

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6.5.2. Net Losses. In the event that there are Net Losses in a calendar quarter, Alimera shall be solely responsible for bearing such Net Losses, subject to Alimera's right to recover [\*] of such Net Losses as provided for in Section 6.5.1.

6.6 Revenues from Third Party Agreements. In the event that Alimera enters into a sublicense or other agreement, or otherwise agrees, with a Third Party, before or after the Profitability Date for a Product, to sell or otherwise transfer some or all of Alimera's rights to a Product, including, but not limited to, marketing rights and/or distribution rights, and Alimera obtains any form of consideration in connection therewith, CDS shall be entitled to receive [\*] of the excess of (i) such consideration (excluding any amounts paid for equity securities of Alimera other than amounts that exceed the fair market value of such securities) over (ii) Alimera's reasonable out-of-pocket costs that are directly and solely incurred to secure such Third Party agreement, promptly after any such consideration is received by Alimera, provided that (1) the fair market value of such securities shall be determined by mutual agreement of both Parties, and (2) in the event that the Parties fail to reach such mutual agreement, the matter shall be resolved by arbitration in accordance with Section 12.7.2 herein. The amount of payment that CDS is entitled to receive from Alimera pursuant to the foregoing shall be deemed royalty for licenses granted by CDS to Alimera under Article 5, provided that Alimera shall have the right to recoup from all or any portion of such payment to CDS any Compounded Development Payment, Compounded Disputed Costs or other amount then owed by CDS to Alimera under this Agreement as pre-payments of royalty.

6.7 Records; Audits.

6.7.1. Each Party shall keep, and shall cause its Affiliates, agents and sublicensees to keep, full and accurate records and books of account containing all particulars that may be necessary for the purpose of calculating Direct Development Costs, Direct Commercialization Costs, Gross Sales, Net Sales, and Net Profits or Net Losses for Products to be received or borne by the Parties pursuant to this Agreement, including, but not limited to, inventory, purchase and invoice records, manufacturing records, sales analysis, general ledgers, financial statements, and tax returns relating to Products. Such books of account, with all necessary supporting data, shall be kept by each Party at its place of business for the three (3) years next following the end of the calendar year to which each shall pertain. Each Party (the "Audited Party") shall permit an independent accounting firm selected by the other Party (the "Auditing Party") and reasonably acceptable to the Audited Party, which acceptance shall not be unreasonably withheld or delayed, to have access during normal business hours to such records as may be reasonably necessary to verify the accuracy of the Audited Party's reports of Direct Development Costs, Direct Commercialization Costs, Gross Sales, Net Sales, and Net Profits or Net Losses as provided herein. All such verifications shall be conducted at the expense of the Auditing Party and not more than once in each calendar year. In the event such audit concludes that adjustments should be made in the Auditing Party's favor, then any appropriate payments (plus accrued interest at a rate announced by the Bank of America as its prime rate in effect on the date that such payment was first due plus three percent (3%) for the period starting from the date the payment was first due ending on the date the payment was made) shall be paid by the Audited Party within thirty (30) days of the date the Audited Party receives the Auditing Party's accounting firm's written report so concluding, unless the Audited Party shall have a good faith dispute as to the conclusions set forth in such written report, in which case the audited Party shall

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provide written notice to the Auditing Party within such thirty (30) day period of the nature of its disagreement with such written report. The Parties shall thereafter, for a period of sixty (60) days, attempt in good faith to resolve such dispute and if they are unable to do so then the matter will be submitted to dispute resolution in accordance with Section 12.7 hereof. The fees charged by such accounting firm shall be paid by the Auditing Party unless the audit discloses that adjustments in favor of the Auditing Party for the period are five percent (5%) or more of the aggregate amount paid or payable by the Audited Party to the Auditing Party during the period, in which case the Audited Party shall pay the reasonable fees and expenses charged by such accounting firm. The Parties agree that all information subject to review under this Section 6.7 is confidential and that it shall cause its accounting firm to retain all such information subject to the confidentiality restrictions of Article 8 hereof.

6.7.2. In addition to the foregoing, Alimera shall permit an independent certified public accountant retained by UKRF to inspect the records and books of account described in Section 6.7.1 during normal business hours and upon reasonable notice to the extent required by the UKRF Licenses. Such right of inspection shall last for two (2) years following the end of the calendar quarter to which such records and books of account pertain, shall be limited solely to those matters directly related to CDS royalty obligations under the UKRF Licenses, and shall be allowed no more than once a year.

ARTICLE 7 INTELLECTUAL PROPERTY

## 7.1 CDS-Prosecuted Patent Rights.

7.1.1. Filing, Prosecution and Maintenance. CDS shall have primary responsibility for and control over the preparation, filing, prosecution and maintenance of (a) any of the CDS Existing Patent Rights, (b) any Patent Rights included within the CDS Improvements, and (c) any Patent Rights included within the Alimera Improvements that fall within the definition of or relate to the CDS Core Technology (collectively, the "CDS-Prosecuted Patent Rights"). For CDS-Prosecuted Patent Rights, CDS shall have the authority to select patent counsel, and to determine the form and content of such prosecution documents and to make all decisions regarding whether to file, prosecute and maintain patents and patent applications, and in which countries to do so.

7.1.2. CDS Patent Costs. Alimera shall be responsible for reimbursement of CDS Patent Costs only in the jurisdictions identified in Exhibit 1.15 as follows: the CDS Patent Costs in such jurisdictions paid up to the first Product Profitability Date shall be Direct Development Costs, as provided in Section 1.34, and shall be paid by CDS and split between CDS and Alimera in accordance with Section 6.3. The CDS Patent Costs paid after the first Product Profitability Date shall be paid by CDS and Alimera shall reimburse CDS [\*] for all such costs paid by CDS within thirty (30) days after the date of invoice by CDS in accordance with Section 4.4. The list of countries identified in Exhibit 1.15 may be amended (i.e., to add or to drop one or more countries) only upon mutual agreement by the Parties. If, after the Effective Date of this Agreement, CDS grants to any Third Party a license to any of the CDS-Prosecuted Patent Rights for which Alimera has continuing reimbursement obligations, thereafter Alimera's share of costs for those particular CDS-Prosecuted Patent Rights shall be reduced on a per capita basis during the term of such license (by way of example, if CDS grants

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a license to one Third Party to any of the CDS-Prosecuted Patent Rights, Alimera's share of costs for those particular CDS-Prosecuted Patent Rights shall be [\*]).

7.1.3. Communication. CDS shall provide Alimera with copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution and maintenance of CDS-Prosecuted Patent Rights in countries identified in Exhibit 1.15. Alimera may provide comments and CDS will give good faith consideration thereto. In order to facilitate Alimera's rights to comment, CDS shall provide copies of all such official correspondence and any proposed responses by CDS at least ten (10) business days prior to any filing or response deadlines. In the event that the Parties have a material disagreement relating to the prosecution or maintenance of any of the CDS-Prosecuted Patent Rights (other than a determination by CDS to abandon any CDS-Prosecuted Patent Rights as described below), CDS shall have the right to decide on the course of action. Thereafter, Alimera may choose not to pay any portion of the CDS Patent Costs associated with the applicable CDS-Prosecuted Patent Rights. In the event that Alimera chooses not to pay for one or more countries, then, with respect to such countries, (a) the license for the applicable CDS-Prosecuted Patent Rights shall automatically terminate, and (b) CDS shall no longer be bound by Section 5.1.2(1), (2), (3) or (4).

7.2 Abandonment. CDS shall not abandon prosecution or maintenance of any CDS-Prosecuted Patent Rights already pending in any country identified in Exhibit 1.15 without notifying Alimera in a timely manner of CDS' intention and reason therefore and providing Alimera with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance of such Patent Rights as set forth below. For avoidance of doubt, for CDS-Prosecuted Patent Rights, CDS has the sole discretion to decide whether or not to file in a country, and a decision not to file in a country shall not be deemed as abandonment of CDS-Prosecuted Patent Rights in that country for purpose of this Article 7. In the event that CDS abandons prosecution or maintenance of CDS-Prosecuted Patent Rights in any country identified in Exhibit 1.15 at any time during the Term of this Agreement, Alimera may assume prosecution responsibility therefor in the name of CDS, and such patent costs shall be paid by Alimera and CDS may reimburse Alimera for [\*] of such patent costs within thirty (30) days after the date of invoice from Alimera (the "CDS Reimbursement Amount"). In the event that CDS fails to reimburse Alimera within the time period as specified above, any future payment to CDS shall be decreased by an amount that is calculated as follows: the amount of the non-reimbursed CDS Reimbursement Amount is multiplied by [\*], and that amount is compounded annually at the compounding rate of [\*] per annum, for any period in which any portion of such costs remains non-reimbursed. CDS may pay all or any portion of the unpaid CDS Reimbursement Amount plus any interest accrued and due at any time.

7.3 Alimera-Prosecuted Patent Rights.

7.3.1. Filing, Prosecution and Maintenance. Alimera shall have primary responsibility for and control over the preparation, filing, prosecution and maintenance of any Patent Rights included within Alimera Improvements that are not CDS-Prosecuted Patent Rights ("Alimera-Prosecuted Patent Rights"). For Alimera-Prosecuted Patent Rights, Alimera shall have the authority to select patent counsel, and to determine the form and content of such

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prosecution documents and to make all decisions regarding whether to file, prosecute and maintain patents and patent applications, and in which countries to do so. Alimera shall be solely responsible for Alimera Patent Costs and such costs shall be neither Direct Development Costs nor Direct Commercialization Costs. Alimera shall provide CDS with copies of all official correspondence (including, but not limited to, applications, office actions, responses, etc.) relating to prosecution and maintenance of Alimera-Prosecuted Patent Rights.

7.3.2. Abandonment. Alimera shall not abandon prosecution or maintenance of any Alimera-Prosecuted Patent Rights in the Territory without notifying CDS in a timely manner of Alimera's intention and reason therefore and providing CDS with reasonable opportunity to comment upon such abandonment and to assume responsibility for prosecution or maintenance of such Alimera-Prosecuted Patent Rights. For avoidance of doubt, for Alimera-Prosecuted Patent Rights, Alimera has the sole discretion to decide whether or not to file in a country, and a decision not to file in a country shall not be deemed as abandonment of Alimera-Prosecuted Patent Rights in that country for purpose of this Article 7. In the event that Alimera abandons prosecution or maintenance of Alimera-Prosecuted Patent Rights in any country in the Territory, CDS may assume prosecution responsibility for such Patent Rights in that country, and thereafter such Patent Rights will cease to being Alimera-Prosecuted Patent Rights and will become CDS-Prosecuted Patent Rights. Notwithstanding the foregoing, if Alimera, acting in good faith, grants a Third Party prosecution rights with respect to any Alimera-Prosecuted Patent Rights, then CDS' rights under this Section 7.2.2 shall be subject to the rights granted to such Third Partv.

7.4 Information Disclosure; Cooperation. Each Party shall disclose and make available to the other Party all material information controlled by such Party that is reasonably necessary for the other Party to perform its obligations and exercise its rights under this Article 7, including the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Article 7. All such information shall be disclosed to the other Party reasonably promptly after it is first developed or learned or its significance is first appreciated. Without limiting the foregoing, each Party agrees to disclose and make available to the other Party all Alimera Improvements and CDS Improvements, as applicable. Neither Alimera or CDS shall publicly disclose any Alimera Improvements before the Party responsible for filing and prosecuting such Improvements has an opportunity to make appropriate patent filings. Each Party agrees to cooperate with the other Party with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Article 7.

7.5 Employees and Sublicensees Assignment of Inventions. Each Party shall cause all of its employees, Affiliates, contractors, sublicensees, consultants, clinical investigators and agents, acting under authority from such Party or its sublicensees, (i) to enter into written agreements pursuant to which each such person or entity assigns to such Party all Improvements and other Inventions that such individual or entity discovers, develops, creates, conceives or reduces to practice in the course of their relationship with such Party or its sublicensees; and (ii) to execute such other documents and take such other actions as may be necessary to effectuate the foregoing assignments. Each Party agrees to undertake to enforce the agreements referenced in this Section 7.3 (including, where appropriate, by legal action).

7.6 Infringement

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7.6.1. Notification. Each party shall promptly report in writing to the other Party during the Term of this Agreement any known infringement or suspected infringement of any of its Patent Rights that covers a Product and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

7.6.2. Prosecution. CDS shall have the initial right, but not the obligation, to initiate or prosecute an infringement or other appropriate suit or action against any Third Party who at any time has infringed or is suspected of infringing (an "Infringer"), any of the CDS Patent Rights covering a Product. CDS shall give Alimera sufficient advance notice of its intent to file said suit and the reasons therefore, and shall provide Alimera with an opportunity to make suggestions and comments regarding such filing; provided, however, that Alimera shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by CDS, and further provided that it shall be within CDS' sole discretion whether to incorporate such suggestions or comments. CDS shall keep Alimera reasonably informed of the status and progress of the litigation. CDS shall have the sole and exclusive right to select counsel for anv such suit and action and shall pay [\*] including, but not limited to, attorneys' fees and court costs. If CDS has not taken legal action or been successful in obtaining cessation of the infringement within (a) ninety (90) days from the date of notice by Alimera under Section 7.4.1; (b) thirty (30) days after Alimera notifies CDS that Alimera would like to move for injunctive relief; or (c) ten (10) days before the expiration of a period of time set by applicable law in which action must be taken with respect to the alleged infringement (e.g., as may be required under the Hatch-Waxman Act and 35 USC Section 271), then subject to any rights granted to B&L under the B&L Agreement, to enforce or prosecute any Patent Rights owned or Controlled by CDS, Alimera shall have the right to bring suit against an Infringer at Alimera's own expense. This right of Alimera to bring suit, as well as to continue an existing suit, is also conditioned on all of the following requirements:

> (i) The allegedly infringing product, device or method (collectively, the "Accused Device") falls within the definition of Product;

(ii) If Alimera owns (or has licensed from a Third Party and has the right to enforce) any patent(s) that reads on the Accused Device practiced by the Infringer, Alimera will include in the complaint one or more claims alleging infringement of all such other patent(s);

(iii) Alimera has provided evidence to CDS that there is a good faith basis to believe that the Accused Device is being prepared for Commercialization or is already Commercialized;

(iv) Alimera shall keep CDS reasonably and timely informed of the pre-litigation and litigation issues and strategy (including, without limitation, furnishing copies of communications, pleading, and other documents and keeping CDS informed of settlement efforts and developments), and shall obtain suggestions and strategy from CDS, including during pre-trial motions and discovery;

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(v) In the instance of litigation issues and strategies pertaining to defenses or setting strategy for the scope of claims, Alimera shall incorporate all reasonable suggestions and strategy from CDS as may be deemed appropriate in the reasonable business judgment of CDS; and

(vi) Except for joining the legal actions described in this Section 7.4.2 as a party at Alimera's request and matters discussed in the following paragraph, CDS shall have no obligation regarding such actions unless required to participate by law or contract. However, CDS shall have the right to participate in any such actions through its own counsel and at its expense.

Upon request of the other Party, either Party shall join as a party to the suit, at its own expense, and shall offer reasonable assistance to the other Party in connection therewith at its own expense. Any damages, royalties, settlement fees or other consideration for infringement resulting from such suit shall be distributed as follows: (i) first, each Party shall be reimbursed for its reasonable out-of-pocket costs paid in connection with the proceeding; and (ii) thereafter, shall be [\*]. Neither Party shall settle any such action or otherwise consent to an adverse judgment in any such action that adversely affects the rights or interests of the other Party under this Agreement, including, without limitation, issues of validity of the CDS Patent Rights, without the prior written consent of the other Party.

7.6.3. Notification of Third Party Claim. Each Party shall promptly report in writing to the other Party during the Term of this Agreement any claim or allegation by any Third Party that the development or Commercialization of any Product infringes the intellectual property rights of any Third Party and shall provide the other Party with all available evidence supporting said infringement or suspected infringement.

7.6.4. Responsibility. Subject to any rights granted to B&L under the B&L Agreement, Alimera shall have the initial right, but not the obligation, to defend any suit or action initiated by any Third Party alleging solely that a Product developed or Commercialized hereunder has infringed, or is suspected of infringing any Third Party intellectual property rights. Upon Alimera's request, CDS shall offer reasonable assistance to Alimera in connection therewith at Alimera's expense. Alimera shall give CDS advance notice of its intent to defend any said suit and shall provide CDS with an opportunity to make suggestions and comments regarding such defense; provided, however, that CDS shall provide any such comments sufficiently in advance of any filing dates to allow for consideration by Alimera, and further provided that it shall be within Alimera's sole discretion whether to incorporate such suggestions or comments. Alimera shall keep CDS reasonably informed of the status and progress of the litigation. Alimera shall have the sole and exclusive right to select counsel for any such suit and action and shall pay all expenses of the suit, including, but not limited to, attorneys' fees and court costs. Alimera shall have the right to settle any such litigation and shall specifically have the right, whether or not litigation commences, to negotiate a license or other rights from any Third Party authorizing the use of Third Party intellectual property rights in connection with Products; provided, however, that Alimera shall not settle any such action, or otherwise consent to an adverse judgment in any such action, or make any admission in any such license and negotiation that adversely affects the rights or interests of CDS under this Agreement, including,

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without limitation, issues of validity of the CDS Patent Rights, without the prior written consent of CDS. Any such license shall be at arm's length and otherwise on terms and conditions as may be deemed appropriate in the reasonable business judgment of Alimera. Alimera shall provide CDS with a copy of any such license promptly after its execution. All reasonable costs incurred in connection with such litigation and any amounts payable to the Third Party relating to Products under such license shall constitute Direct Commercialization Costs as follows: (i) any litigation, negotiation or settlement-related costs and expenses or up-front payments shall be deemed to be a Direct Commercialization Cost of Product or Products as reasonably allocated by Alimera in good faith, subject to the dispute resolution procedures provided for in Section 12.7; (ii) any royalties on net sales or similar payments calculated by reference to sales shall be allocated to Products on a Product-by-Product and country-by-country basis; (iii) any other amounts (e.g., milestone payments or patent reimbursement fees) shall be reasonably allocated by Alimera to one or more Products in good faith, subject to the dispute resolution procedures provided for in Section 12.7. If Alimera recovers any damages or any other payments, by way of settlement or otherwise, in connection with any counterclaim made by it in any such actions, such damages shall be considered "Net Sales" for purposes of this Agreement.

If Alimera does not defend a claim, suit or proceeding as set forth above within ninety (90) days of the date Alimera was reasonably aware or notified of the Third Party claim alleging infringement (or within such shorter period as may be necessary for submitting or filing a response), then CDS may, in its sole discretion, elect to defend such claim, suit or proceeding, using counsel of its own choice and the provisions of Section 7.6.4 shall apply as if the term "CDS" were changed to "Alimera" and the term "Alimera" were changed to "CDS."

7.7 Marking. Alimera and any Affiliates or sublicensees shall mark all Products with the numbers of all patents included in CDS Technology that cover the Products. Without limiting the foregoing, all Products shall be marked in such a manner as to conform with the patent laws of the country to which such Products are shipped or in which such products are sold, including, but not limited to, the requirements of 35 U.S.C. Section 287.

7.8 Trademarks. Alimera shall be free to adopt, use and register in any trademark offices any trademarks for use with a Product in its sole discretion. Subject to Section 11.5.2, Alimera shall own all right, title and interest in and to any such trademark in its own name during and after the Term of this Agreement.

7.8.1. The "Medidur" Mark. CDS hereby grants to Alimera a royalty-free non-exclusive right and license, with right to sublicense, to use the "MEDIDUR" mark Controlled by CDS on or in connection with any Products marketed, distributed or sold pursuant to this Agreement. Alimera shall not use the "MEDIDUR" mark in direct association with another mark such that the two marks appear to be a single mark or in any other composite manner with any marks of Alimera or any Third Party. Alimera shall cause to appear on all items bearing the "MEDIDUR" mark such legends, markings and notices as may be required by applicable law or reasonably requested by CDS to establish, perfect, defend or exploit the proprietary character of the "MEDIDUR" mark. Alimera shall not grant, attempt to grant, or record anywhere, a security interest in the "MEDIDUR" mark. Alimera hereby assigns and will assign any goodwill associated with its use of the "MEDIDUR" mark to CDS. CDS has the right to control the quality of the Products Commercialized in connection with the commercial

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exploitation of the MEDIDUR Mark as follows: (1) CDS may, in its sole discretion, request and carry out periodic inspections of the operation of Alimera, its Affiliates, subcontractors and sublicensees, and (2) Alimera agrees to reasonably cooperate, and to cause its Affiliates, subcontractors and sublicensees to cooperate, with such periodic inspections of its operations upon reasonable prior written notice by CDS. Alimera acknowledges and agrees that the "MEDIDUR" mark shall remain the property of CDS. ALIMERA ACKNOWLEDGES AND AGREES THAT THE "MEDIDUR" MARK IS PROVIDED ON AN "AS IS" BASIS AND THAT CDS MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES WHATSOEVER, EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT THERETO INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF TITLE, VALIDITY, ENFORCEABILITY OR NON-INFRINGEMENT. CDS is not obligated to (i) file any application for registration of the "MEDIDUR" mark, or to secure any rights in the "MEDIDUR" mark, (ii) to maintain the "MEDIDUR" mark, or (iii) to police or pursue (including for infringement) any Third Parties using the "MEDIDUR" mark.

7.9 UKRF Licenses and B&L Agreement. CDS shall not amend or modify any of the UKRF Licenses or the B&L Agreement, or waive any right thereunder, in any manner that would adversely affect Alimera's rights hereunder without the prior written authorization of Alimera.

### ARTICLE 8 CONFIDENTIALITY

8.1 Confidentiality. Except as otherwise provided in this Article 8, each Party shall maintain Confidential Information of the other Party in confidence and shall not disclose Confidential Information of the other Party to any Third Party and shall not use Confidential Information of the other Party except as expressly authorized under this Agreement. "Confidential Information" shall mean any and all information (whether in written, electronic, visual, verbal or other form) received from the other Party or its representatives, including, but not limited to, all information relating to any technology, product, method, process or intellectual property of such disclosing Party (including, but not limited to, Patent Rights, and other owned or licensed intellectual property rights, data, Know-How, samples, technical and non-technical materials and specifications), as well as any business plan, financial information, research data or results, or other confidential commercial information of or about such disclosing Party; provided, however, that Confidential Information shall not include any information that: (a) is or becomes part of the public domain other than by unauthorized acts or omissions of the Party obligated not to disclose such Confidential Information or its employees, directors, officers, or agents (collectively, the "Receiving Party"); (b) can be shown by written documents to have been disclosed to the Receiving Party by a Third Party; provided, however, that such Third Party had no obligation of confidentiality or non-use to the disclosing party with respect to such Confidential Information; (c) can be shown by written documents to have been in the possession of the Receiving Party prior to disclosure by the disclosing Party; provided, however, that such Confidential Information was not obtained directly or indirectly from the other Party to this Agreement pursuant to a confidentiality agreement; or (d) is required to be disclosed by the Receiving Party pursuant to interrogatories, requests for information or documents, subpoena, civil investigative demand issued by a court or governmental agency or as otherwise required by law; provided, however, that in connection with this clause (d) the Receiving Party shall notify the other Party immediately upon receipt thereof and give such other Party sufficient advance

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notice to permit it to seek a protective order or other similar order with respect to such Confidential Information; and provided, further, that the Receiving Party furnishes only that portion of the Confidential Information that it is advised by counsel is legally required whether or not a protective order or other similar order is obtained by the other Party. Notwithstanding any other provisions of this Article, (1) Alimera Know-How shall be Confidential Information of Alimera and CDS Technology shall be Confidential Information of CDS; and (2) each Party shall treat the terms and conditions of this Agreement as Confidential Information of the other Party.

8.2 Disclosure. To the extent that it is reasonably necessary, a Party may disclose Confidential Information it is otherwise obligated under this Article 8 not to disclose to its employees on a need-to-know basis and on condition that such employees agree in writing to non-use and non-disclosure obligations essentially the same as those set forth herein and to keep the Confidential Information confidential to the same extent as such Party is required to keep the Confidential Information confidential. In addition, a Party may disclose such Confidential Information: (a) to government or other regulatory authorities to the extent that such disclosure is required by law, regulation or order (i) in connection with the filing, prosecution or maintenance of patents for which the Party disclosing the Confidential Information has responsibility or is permitted under this Agreement to file, prosecute and maintain, or (ii) to obtain authorizations to conduct clinical trials of, and to Commercialize, Products pursuant to this Agreement; (b) to any applicable securities exchange or the National Association of Securities Dealers ("NASD"), as required by applicable law or any listing agreement with, or the rules and regulations of, any applicable securities exchange or NASD, provided, that, the Party who makes the filing will seek confidential treatment for such filing; (c) in confidence, to lawyers, accountants and sources of funding of a Party and (d) to sublicensees in connection with any sublicense of the technology or intellectual property, or portion thereof, licensed hereunder as permitted under this Agreement. In addition, a Party may disclose the terms of this Agreement to any investors or potential investors, lenders, and other potential financing sources, or to a Third Party in connection with a merger or acquisition or proposed merger or acquisition or a license or proposed license of the technology or intellectual property licensed hereunder, and to Affiliates, attorneys, accountants, stockholders, investment bankers, advisers or other consultants of the foregoing, in each case provided that the Person to which such disclosure is made is obligated by written agreement to keep such information confidential on essentially the same terms as set forth herein and to use such Confidential Information solely to evaluate such investment, financing, acquisition, merger or license.

### ARTICLE 9 REPRESENTATIONS AND WARRANTIES

9.1 Representations and Warranties of CDS. CDS represents and warrants as of the Effective Date that:

(a) CDS is a corporation duly organized, validly existing and in corporate good standing under the laws of Delaware;

(b) CDS has the legal right, authority and power to enter into this Agreement, and to extend the rights and licenses granted to Alimera in this Agreement;

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(c) CDS has taken all necessary action to authorize the execution, delivery and performance of this  $\mbox{Agreement};$ 

(d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of CDS enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

(e) the performance of its obligations under this Agreement will not conflict with its charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party;

(f) CDS is the sole and exclusive owner or the licensee of CDS Existing Patent Rights;

(g) to the best of CDS' knowledge, no claim has been threatened or asserted that the practice of any patent or patent application listed in Exhibit 1.11A infringes patent rights of any Third Party;

(h) CDS has not received any complaint, demand or notice from a Third Party in writing challenging the validity or enforceability of any patent listed in Exhibit 1.11A;

(i) CDS has no present intention [\*] any patent listed in Exhibit1.11A and has not instructed its patent counsel or taken any other actions [\*] any patent listed in Exhibit 1.11A;

(j) CDS is in compliance in all material respects with the UKRF Licenses and the B&L Agreement; to CDS' knowledge, there is no noncompliance by UKRF or B&L under the UKRF Licenses and the B&L Agreement, respectively, other than noncompliance that would not adversely affect Alimera's rights hereunder; and

(k) neither CDS nor any of its Affiliates has initiated for CDS a filing for protection under the bankruptcy laws, an assignment for the benefit of creditors, appointment of a receiver or trustee over its property or any similar undertaking.

9.2 Representations and Warranties of Alimera. Alimera represents and warrants as of the Effective Date that:

(a) Alimera is a corporation duly organized, validly existing and in corporate good standing under the laws of Delaware.

(b) Alimera has the legal right, authority and power to enter into this Agreement, and to extend the rights and licenses granted to CDS in this Agreement;

(c) Alimera has taken all necessary action to authorize the execution, delivery and performance of this Agreement;

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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(d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Alimera enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws, affecting creditors' and contracting parties' rights generally and except as enforceability maybe subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

(e) the performance of its obligations under this Agreement will not conflict with Alimera's charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party; and

(f) to the knowledge of Alimera, Alimera is the sole and exclusive owner of the Alimera Know-How.

9.3 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY CDS TECHNOLOGY, CDS KNOW-HOW, ALIMERA IMPROVEMENTS, ALIMERA KNOW-HOW, GOODS, SERVICES OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, SCOPE AND NON-INFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING.

9.4 Limited Liability. EXCEPT FOR THEIR RESPECTIVE OBLIGATIONS UNDER ARTICLE 8 or ARTICLE 10, NEITHER CDS NOR ALIMERA WILL BE LIABLE WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY PUNITIVE, EXEMPLARY, INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES OR LOST PROFITS.

# ARTICLE 10 INDEMNITY

10.1 Cross Indemnity. Each Party (the "Indemnifying Party") agrees to defend, indemnify and hold the other party (the "Indemnified Party"), its Affiliates and their respective directors, officers, employees and agents and their respective heirs and assigns harmless from all Third Party claims, actions, losses, damages, liabilities or expenses (including, but not limited to, reasonable attorneys' fees) (each, a "Loss") arising as a result of (a) a breach by the Indemnifying Party of any of its representations, warranties or obligations under this Agreement, (b) actual or asserted violations of any applicable law or regulation by the Indemnifying Party or any of its employees, Affiliates, sublicensees, consultants, or other agents in connection with the research, development, manufacture, distribution, marketing, promotion, sale, or use of Products, or the reporting requirements for Products, including, but not limited to, any allegation or determination that a Product has been adulterated, misbranded, mislabeled or otherwise is not in compliance with any applicable law or regulation, or (c) except as provided in Section 7.4.4 or 10.5, bodily injury, death, property damage or other harm or damage attributable to the research, development, manufacture, distribution, marketing, promotion, sale or use of any Products by the Indemnifying Party or its employees, Affiliates, sublicensees, consultants, or other agents.

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10.2 Limitation on Indemnity Obligations. A Party, its Affiliates and their respective directors, officers, employees and agents shall not be entitled to the indemnities set forth in Sections 10.1 to the extent the Loss for which indemnification is sought was caused by the negligence, or by the reckless or intentional misconduct or omission, of such Party or its directors, officers, employees or agents.

10.3 Procedure. If an Indemnified Party intends to claim indemnification under Article 10, the Indemnified Party shall notify the Indemnifying Party of any Loss in respect of which the Indemnified Party intends to claim such indemnification, and the Indemnifying Party shall assume the defense thereof with counsel mutually satisfactory to the Parties. The failure to deliver notice to the Indemnifying Party within a reasonable time after the commencement of any such action, shall relieve such Indemnifying Party of liability to the Indemnified Party under Article 10 only to the extent that the delay adversely affects Indemnifying Party's rights or ability to defend such claim or action, but the failure so to deliver notice to the Indemnifying Party will not relieve the Indemnifying Party of any liability that it may have to any Indemnified Party otherwise than under Article 10. The Indemnified Party under Article 10 shall provide reasonable assistance to the Indemnifying Party and its legal representatives, at the Indemnifying Party's expense, in the investigation of any action, claim or liability covered by this indemnification. The Indemnifying Party shall additionally be liable to pay the reasonable legal costs and attorneys' fees incurred by the Indemnified Party in establishing its claim for indemnity. Except as provided in the last sentence of this Section 10.3, the indemnity agreement in this Article 10 shall not apply to amounts paid in settlement of any Loss if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be withheld unreasonably or delayed. Indemnifying Party shall not, without the written consent of Indemnified Party, settle or compromise any Loss or consent to the entry of any judgment with respect to any Loss (a) that does not release Indemnified Party from all liability with respect to such Loss or (b) which may materially adversely affect Indemnified Party or under which Indemnified Party would incur any obligation or liability, other than one as to which Indemnifying Party has an indemnity obligation hereunder. If Indemnifying Party, within ten (10) days of receiving notice of a Loss or such shorter period as may be necessary for submitting or filing a response, fails to assume the defense of such Loss or fails to notify Indemnified Party that is assuming such defense, Indemnified Party shall have the right to assume the defense, compromise or settlement of such Loss at the risk and expense of Indemnifying Party.

10.4 Insurance. Each Party shall maintain, and shall cause its Affiliates and each sublicensee conducting activities under this Agreement to maintain, at such Party's, an Affiliate's, or sublicensee's sole expense, appropriate product liability insurance coverage in amounts reasonably determined by the Party from time to time but at least sufficient to insure against claims which may arise from the performance of obligations or exercise of rights granted under this Agreement or from indemnification obligations under this Article 10, but in no event shall a Party's insurance coverage be in an amount less than \$5,000,000 per occurrence and \$10,000,000 annual aggregate. The policy of insurance shall contain a provision of non-cancellation except upon the provision of thirty (30) days notice to the other Party. The policy of insurance with respect to any Product that would, absent the licenses herein, infringe a Valid Claim under a patent licensed under one or more of the UKRF Licenses shall contain an endorsement naming UKRF, and the University of Kentucky (and its Board of Trustees, agents, officers, and employees) as additional insureds. Each Party shall maintain such insurance

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commencing on the Effective Date and for so long as it continues to research, produce, develop, manufacture, distribute, sell or use the Products, and thereafter for so long as each Party maintains insurance for itself covering such manufacture or sales.

10.5 Product Liability Claims. If either Party incurs any losses, costs, damages (including amounts paid in settlement of claims), fees (including reasonable attorneys' fees) or expenses arising out of any Third Party claim relating to injuries or death resulting from the use of any Product developed or Commercialized pursuant to this Agreement, then such losses, costs, damages, fees or expenses that are not attributable to the gross negligence and/or willful misconduct of a Party and are not covered by an insurance policy ("Product Liability Losses") shall be Direct Commercialization Costs. If CDS incurs Product Liability Losses, Alimera shall reimburse CDS for [\*] of the Product Liability Losses within forty-five (45) days of receipt of a request for reimbursement for such Product Liability Losses. If either Party incurs any losses, costs, damages (including amounts paid in settlement of claims), fees (including reasonable attorneys' fees) or expenses arising out of any Third Party claim relating to injuries or death resulting from the use of any Product developed or Commercialized pursuant to this Agreement, then to the extent such losses, costs, damages, fees or expenses are attributable to the gross negligence and/or willful misconduct of a Party, such Party shall bear [\*] of such losses, damages, fees or expenses.

### ARTICLE 11 TERM AND TERMINATION

11.1 Term. If not earlier terminated as provided in this Article 11, the term of this Agreement (the "Term") shall commence on the Effective Date and expire upon the later of (i) ten (10) years after the Effective Date, or (ii) the expiration or abandonment of the last Valid Claim included in the CDS Patent Rights, or (iii) as long as Alimera, any Affiliate of Alimera or any sublicensee is selling a Product in any part of the Territory.

11.2 Termination for Default by Either Party. Either Party may terminate this Agreement (i) upon the occurrence of a breach of a material term of this Agreement (other than a material breach described in clause (ii) below or in Section 11.3, 11.4 or 11.5) if the breaching Party fails to remedy such breach within thirty (30) days after notice thereof by the non-breaching Party or, with respect to a breach (other than a failure to make a payment) that cannot be cured within such period, then such longer period (up to 90 days) as may be reasonably necessary, using Commercially Reasonable Efforts, to cure the breach, or (ii) if the other Party files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it and such proceeding remains undismissed or unstayed for a period of more than sixty days. Upon termination, the non-breaching Party shall, subject to the dispute resolution procedures set forth in Section 12.7, have the right, in its sole discretion, to seek any other rights or remedies available to it at law or in equity.

11.3 Termination for Non-Payment of Development Payment. Either Party (the "Terminating Party") may terminate this Agreement upon the other Party's failure to make a timely payment of all or a portion of any of its Development Payments, or if the other Party has outstanding Compounded Development Payments and/or Compounded Disputed Costs under

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Section 6.3 (the "Non-Terminating Party"); provided, however, that the Terminating Party gives notice of termination to the Non-Terminating Party, and the Non-Terminating Party fails to pay all such payments under this Agreement within thirty (30) days of receiving such notice (provided that each Party has a one-time right to use sixty (60) days to cure hereunder). The Terminating Party's sole and exclusive remedy for the Non-Terminating Party's failure to make any of its Development Payments, Compounded Development Payments and/or Compounded Disputed Costs, shall be the following: (i) the Terminating Party may terminate this Agreement under this Section 11.3, (ii) the amounts of Compounded Development Payments plus Compounded Disputed Costs owed by each Party shall be determined, as of the date of termination (provided that solely for purposes of this Section 11.3, the amounts of Compounded Development Payments and Compounded Disputed Costs shall be calculated as set forth in Sections 6.3.2 and 6.3.3 except that the words  $[\,\star\,]$  shall be substituted in place of  $[\,\star\,]$  in Sections 6.3.2 and 6.3.3) and the Party with the larger total amount of such costs shall pay the other Party the difference between the paying Party's total amount of such costs and the other Party's total amount of such costs (the "Termination Amount"), provided that, from and after the date of termination, interest on any unpaid Termination Amount shall accrue at [\*] compounded annually, until the full Termination Amount plus accrued interest has been paid; further provided that the accrual of such interest or payment shall not preclude the Terminating Party from seeking full payment of amounts owed under this Section 11.3, and (iii) if (A) CDS is the Terminating Party, (B) Alimera has paid more than  $\left[\star\right]$ pursuant to Sections 6.1-6.3, and (C) CDS terminates this Agreement pursuant to this Section 11.3 and thereafter directly or through an Affiliate or a Third Party Commercializes any Product that was under development pursuant to the Development Plan at the time of termination, then (x) CDS shall, after the CDS Profitability Date, on a quarterly basis, pay Alimera [\*] of CDS Net Income realized by CDS that is attributable to such Product, until the aggregate amount of such payments equals [\*] of the total amount of Development Payments and Determined Disputed Costs paid by Alimera pursuant to Sections 6.1-6.3 (provided, however, that such total amount of Development Payments and Determined Disputed Costs paid by Alimera shall exclude (1) any amount Alimera paid to CDS upon termination pursuant to this Section 11.3, and (2) any amount Alimera paid to CDS solely due to the [\*] multiplier and the [\*] annual compounding pursuant to Sections 6.3.2 and 6.3.3); further provided that in the event that there are CDS Net Losses in any calendar quarter after the CDS Profitability Date, any payment to Alimera shall be offset by such CDS Net Losses, and (y) Alimera shall not, for as long as CDS makes, or is obligated to make, payment to Alimera pursuant to the foregoing, Develop or Commercialize, or license or otherwise assist an Affiliate or a Third Party to Develop or Commercialize, any product that is Approved or designed to be Approved (1) to treat DME or (2) to deliver a corticosteroid by injection, implantation or other direct delivery method to the posterior portion of the eye. Solely for purposes of the preceding sentence, the term "Develop" shall mean performance of human clinical trials for a product.

11.4 Termination for Failure to Approve an Initial Development Plan. Either Party may terminate this Agreement in the event that an initial Development Plan is not approved within 30 days after the Effective Date. If either Party chooses to terminate this Agreement under this Section 11.4, such termination shall be the sole and exclusive remedy for each Party for failure to approve an initial Development Plan, provided that CDS shall repay to Alimera [\*] in accordance with the terms of the Secured Promissory Notes from CDS to Alimera dated October 19, 2004, November 18, 2004 and December 22, 2004.

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11.5 Termination for Abandonment. For purposes of this Section 11.5, "Abandonment" by a Party or to "Abandon" shall mean either (i) delivery of a written election by a Party to abandon this Agreement with respect to a Product or (ii) the event in which the aggregate amount of a Party's overdue Development Payments and/or overdue Determined Disputed Costs exceeds [\*] with respect to such Product in the Territory, and the Non-Paying Party fails to pay all Compounded Development Payments and Compounded Disputed Costs then owing related to such Product in the Territory under this Agreement within thirty (30) days of receiving written request of payment of such outstanding Compounded Development Payments and Compounded Disputed Costs from the other Party. If a Party Abandons a Product pursuant to this Section 11.5, then the other Party's sole remedy shall be termination with respect to such Product pursuant to this Section 11.5. Solely for purposes of this Section 11.5 (including 11.5.1 and 11.5.2), the term "Product" shall have the meaning set forth in Section 1.77 except that in (E) and (4) the words "in a particular country" shall be omitted, in the next to last sentence the words "in each country" shall be omitted, and in the last sentence example (ii) shall be omitted.

11.5.1. Effect of Abandonment by CDS. In the event that CDS Abandons a Product, Alimera shall terminate this Agreement with respect to that Product in the Territory for Abandonment of that Product by CDS under this Section 11.5. Upon such termination, Alimera shall choose one of the following two options: (1) the Parties will enter into a license agreement under which CDS grants Alimera an exclusive license under the CDS Technology to make, have made, use, offer to sell, sell, and import such Product in the Collaboration Field, and, in consideration of the grant of such license, CDS shall receive a royalty of [\*] of Net Sales of such Product in the Territory (after recovery by Alimera of all Development Payments and Determined Disputed Costs owed by CDS to Alimera pursuant to Sections 6.3.2 and 6.3.3 as pre-payments of royalty, without giving effect to the [\*] multiplier or the [\*] annual compounding otherwise provided for in Sections 6.3.2 and 6.3.3) and the license shall include those other terms and conditions set forth on Exhibit 11.5.1, or (2) CDS shall pay to Alimera any Compounded Development Payments or Compounded Disputed Costs that CDS owes Alimera as of the date of termination, after deducting the amounts of any outstanding Compounded Development and/or Compounded Disputed Costs that Alimera owes CDS as of that date (the "CDS Abandonment Amount") (provided that solely for purposes of this Section 11.5.1 and Section 11.5.2, the amounts of Compounded Development Payments and Compounded Disputed Costs shall be calculated as set forth in Sections 6.3.2 and 6.3.3 except that the words [\*] shall be substituted in place of [\*] in Sections 6.3.2 and 6.3.3) further provided that, from and after the date of termination, interest on any unpaid CDS Abandonment Amount shall accrue at  $[\,{}^{\star}\,]$  (rather than at  $[\,{}^{\star}\,])\,,$  compounded annually, until such costs have been paid. In the event that the Parties enter into a license agreement pursuant to this Section 11.5.1(a), upon execution of such license agreement and at Alimera's request: (a) any and all Confidential Information and materials solely related to such Product provided by Alimera pursuant to this Agreement shall be promptly returned by CDS to Alimera, (b) CDS shall promptly deliver to Alimera copies of all Clinical IP owned or Controlled by CDS and necessary or useful to the development or Commercialization of such Product and CDS shall not use any such Clinical IP thereafter for any regulatory applications or filings for such Product, provided that the foregoing shall not prevent CDS from using such Clinical IP for other Products or from performing preclinical and clinical studies or other research of any nature, including research that reproduces data contained in the Clinical IP, or from using the results of

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such research in regulatory applications or filings or for any other purpose, (c) any regulatory filings for such Product which have been submitted in CDS' name which have not been transferred to Alimera, subject to FDA approval, will be transferred to Alimera's name, and (d) CDS will assign to Alimera all of its right, title and interest in any trademark under which CDS shall solely have marketed such Product or registered for use solely with such Product together with the goodwill associated therewith. Termination of this Agreement with respect to such Product and the options described this Section 11.5.1 with respect to such Product shall be Alimera's sole and exclusive remedy for Abandonment of such Product by CDS. In the event that, (x) Alimera chooses option (2) upon termination with respect to a Product and CDS pays to Alimera the amounts described therein, and (y) at the time of such termination, no Product designed for treating DME is being developed pursuant to a Development Plan or being Commercialized pursuant to the Commercialization Budget, then CDS shall no longer be bound by Section 5.1.2(1), (2), (3) or (4) with respect to that Product.

11.5.2. Effect of Abandonment by Alimera. In the event that CDS terminates this Agreement with respect to a Product in the Territory for Abandonment of that Product by Alimera under this Section 11.5, the rights and licenses granted to Alimera pursuant to Article 5 shall terminate with respect to that Product in the Territory and the Parties shall negotiate in good faith a license agreement under which Alimera shall grant to CDS a non-exclusive license to any Alimera Know-How related to such Product. After termination with respect to such Product as set forth in this Section 11.5 and at CDS' request: (a) any and all Confidential Information and materials solely related to such Product provided by CDS pursuant to this Agreement shall be promptly returned by Alimera to CDS, (b) Alimera shall promptly deliver to CDS copies of all Clinical IP owned or Controlled by Alimera and necessary or useful to the development or Commercialization of such Product and Alimera shall not use any such Clinical IP thereafter for any regulatory applications or filings for such Product, provided that the foregoing shall not prevent Alimera from using such Clinical IP for other Products or from performing preclinical and clinical studies or other research of any nature, including research that reproduces data contained in the Clinical IP, or from using the results of such research in regulatory applications or filings or for any other purpose, (c) if Alimera has applied for or obtained any Approvals in any country for the Product, then Alimera shall, to the extent legally permissible, take all additional action reasonably necessary to assign all of its right, title and interest in and transfer possession and control to CDS of such applications or Approvals, (d) any regulatory filings for the Product which have been submitted in Alimera's name, subject to FDA approval, will be transferred to CDS' name, (e) Alimera will assign to CDS all of its right, title and interest in any trademark under which Alimera shall solely have marketed the Product or registered for use solely with such Product together with the goodwill associated therewith, and (f) CDS shall no longer be bound by Section 5.1.2(1), (2), (3) or (4) with respect to the Product Abandoned by Alimera. Termination of this Agreement with respect to the Product shall be CDS' sole and exclusive remedy for Abandonment of that product by Alimera, except that Alimera shall promptly pay to CDS all Compounded Development Payments and/or Compounded Disputed Costs that Alimera owes CDS as of the date of termination, after deducting the amounts of any outstanding Compounded Development and/or Compounded Disputed Costs that CDS owes Alimera as of that date (the "Alimera Abandonment Amount"), provided that, from and after the date of termination, interest on any unpaid Alimera Abandonment Amount shall accrue at [\*] (rather than at [\*]), compounded annually, until such costs have been paid; further

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[\*]- Indicates material that has been omitted and for which confidential treatment has been requested. All such information has been filed with the Commission pursuant to Rule 24b-2 promulgated under the Securities and Exchange Act of 1934, as amended.

provided that the accrual of such interest or payment shall not preclude CDS from seeking full payment of amounts owed under this Section 11.5.2.

11.6 Effect of Expiration or Termination of the Agreement. Except as expressly provided herein, the expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination and all rights and licenses granted under this Agreement shall be terminated. In the event of termination of this Agreement pursuant to Section 11.2, (a) any and all Confidential Information and materials provided by the non-breaching Party to the breaching Party pursuant to this Agreement shall be promptly returned by the breaching Party to the non-breaching Party, and (b) the breaching Party shall not use any Clinical IP arising from the activities conducted under this Agreement at any time thereafter; provided that the foregoing shall not prevent the breaching Party from performing preclinical and clinical studies or other research of any nature, including research that reproduces data contained in the Clinical IP, or from using the results of such research in regulatory applications or filings or for any other purpose.

11.7 Survival of Provisions Upon Expiration or Termination. The provisions of Articles 8, 10 and 11, and Sections 5.2 (in the event of termination of this Agreement by CDS under Section 11.5.2), 5.4, 5.5, 5.6, 5.9, 9.3, 9.4, 11.5.1 (in the event of termination of this Agreement by Alimera under Section 11.5), 11.5.2 (in the event of termination of this Agreement by CDS under Section 11.5), 11.6, 12.5, 12.6 and 12.7 shall survive the expiration or termination of this Agreement for any reason.

## ARTICLE 12 MISCELLANEOUS

### 12.1 Interpretation.

(a) If an ambiguity or a question of intent or interpretation arises with respect to this Agreement, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.

(b) Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "but not limited to." The word "will" shall be construed to have the same meaning and effect as the word "shall." Unless the context requires otherwise, (A) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (B) any reference to any laws herein shall be construed as referring to such laws as from time to time enacted, repealed or amended, (C) any reference herein to any Person shall be construed to include the Person's permitted successors and assigns, (D) the words "herein", "hereof and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof unless specifically stated, (E) any reference herein to the words "mutually agree" or "mutual written agreement" shall not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as

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such Party may determine in such Party's sole discretion and unless otherwise stated; and (F) all references herein to Articles, Sections or Schedules shall be construed to refer to Articles, Sections and Schedules of this Agreement unless otherwise noted.

12.2 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the consent of the other Party; provided, however, that either Party may, without such consent, assign its rights and obligations under this Agreement in connection with a Change of Control of such Party; provided, however, that such Party's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

12.3 Severability. Each Party hereby agrees that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties hereto shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

12.4 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery or courier) or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon receipt by the addressee.

If to CDS:	Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472 Attention: President Fax: (617)-926-5050
With a copy to:	Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472 Attention: General Counsel Fax: (617) 926-5050
With a copy to:	Ropes & Gray LLP One International Place Boston, MA 02110 Attention: Susan Galli, Esq.

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Fax: (617) 951-7050

If to Alimera:	Alimera Sciences, Inc.
	6120 Windward Parkway, Suite 290
	Alpharetta, GA 30005
	Attention: President
	Fax: (678) 990-5744

With a copy to: Hutchison & Mason PLLC 3110 Edwards Mill Road, Suite 100 Raleigh, NC 26712 Attention: William N. Wofford Fax: (919) 829-9696

12.5 Governing Law and Venue. This Agreement shall be governed by, construed and enforced in accordance with the laws of the State of New York, without regard to any choice of law principle that would dictate the application of the laws of another jurisdiction. Any suit brought by Alimera arising under or relating to this Agreement shall be brought in a court of competent jurisdiction in the Commonwealth of Massachusetts, and Alimera hereby consents to the jurisdiction of the state and federal courts sitting in the Commonwealth of Massachusetts. Any suit brought by CDS arising under or relating to this Agreement shall be brought in a court of competent jurisdiction in the state of Georgia, and CDS hereby consents to the jurisdiction of the state and federal courts sitting in the state of Georgia. Each Party agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of the specified courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in any inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such court does not have any jurisdiction over such Party.

12.6 Compliance with Applicable Laws. The Parties shall use their best efforts to comply with all provisions of any applicable laws, regulations, rules and orders relating to the license granted and to the testing, production, transportation, export, packaging, labeling, sale or use of Products. The Parties shall use their best efforts to obtain written assurances regarding export and re-export of technical data (including Products made by use of technical data) as may be required by the Office of Export Administration Regulations. Notwithstanding any other provision of this Agreement, each Party (and each Affiliate and agent of the Party) may disclose the tax treatment and tax structure of the transaction and all materials of any kind (including, but not limited to, opinions and other tax analyses) that are provided to the Party relating to such tax treatment and tax structure as contemplated by section 1.6011-4(b)(3)(iii) of the Code of Federal Regulations.

12.7 Dispute Resolution. Any disputes, other than disputes regarding the construction, validity or enforcement of patents (which disputes shall be resolved by Section 12.5), arising between the Parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, or the performance by either Party of its obligations hereunder, whether before or after termination of this Agreement, shall be resolved as follows:

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12.7.1. Senior Management. If the dispute cannot be resolved by the Primary Contact Persons in accordance with Section 3.4 hereof or then in accordance with Section 2.4, the Primary Contact Persons shall promptly notify the chief executive officer of each Party (or their designee), who shall meet in person at a mutually acceptable time and location or by means of telephone or video conference within sixty (60) days of such notice and attempt to negotiate a settlement.

12.7.2. Arbitration. If the chief executive officers are not able to resolve the dispute within thirty (30) days of their first meeting or within such extended period as they agree upon, either Party may submit the matter to binding arbitration in accordance with this Section 12.7.2. Except as specified below, the arbitration shall be conducted in accordance with the rules of, and under the auspices of, the American Arbitration Association (the "AAA"). The arbitration will be conducted by a single arbitrator with relevant technical expertise who is jointly selected by the Parties or, if the Parties cannot mutually agree, is selected by the AAA administrator and is not employed by and does not have a material financial relationship with, a Party or any of its Affiliates. If Alimera is the claimant, the location of the arbitration shall be in the Boston, Massachusetts and if CDS is the claimant, the location of the arbitration shall be in Atlanta, Georgia. This Agreement shall remain in effect pending completion of the proceedings brought under this Section 12.7.2. Within ten (10) Business Days after the arbitrator is selected, each Party shall submit to the arbitrator that Party's proposed resolution of the dispute and justification therefor. All arbitration proceedings must be completed within 30 days after the arbitration is convened. The Parties hereby agree that the arbitrator has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator deems reasonable and necessary with or without petition therefor by the Parties as well as the final ruling and judgment. Rulings shall be issued by written order summarizing the arbitration proceedings. Any judgment or award by the arbitrator in any dispute shall have the same force and effect as the final judgment of a court of competent jurisdiction. Nothing in this arbitration clause shall prevent either Party from seeking a pre-award attachment of assets or preliminary relief to enforce its rights in intellectual property or confidentiality obligations under this Agreement, or to enjoin any event that might cause irreparable injury, in a court of competent jurisdiction prior to an award on the merits by the arbitrator.

12.8 Use of Name/Publicity. Except as otherwise expressly permitted under this Agreement, neither Party shall (i) use the name of the other in any press releases, public announcements or other publicity or advertising materials, or (ii) disclose the existence or terms of this Agreement, in each case, without written approval of the other Party. The Parties agree that a public announcement of the execution of this Agreement shall be made in the form of a mutually acceptable press release within ten Business Days after the Effective Date. Thereafter, each Party, with the prior written consent from the other Party, shall have the right to publicly announce the achievement of any event relating to Product deemed newsworthy by such Party and to publish results of clinical trials and other publications relating to the Products, provided that no such publications by one Party shall include Confidential Information of the other Party.

12.9 Entire Agreement. This Agreement, together with the Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. In the event of any conflict or inconsistency

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between any provision of any Exhibits hereto and any provision of this Agreement, the provisions of this Agreement shall prevail. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties hereto. The Confidentiality Agreement between Alimera and CDS with an effective date of August 17, 2004 remains effective until the Effective Date of this Agreement, whereupon the provisions of such agreement shall survive to the extent set forth in that agreement.

12.10 Headings. The captions to the several Articles and Sections hereof and Exhibits hereto are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

12.11 Independent Contractors. It is expressly agreed that CDS and Alimera shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither CDS nor Alimera shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party to do so.

12.12 Waiver. The waiver by either Party hereto of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

12.13 Counterparts. This Agreement may be executed by facsimile and/or in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[signature page to follow]

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IN WITNESS WHEREOF, the Parties have executed this Collaboration Agreement as of the date first set forth above. ALIMERA SCIENCE, INC. CONTROL DELIVERY SYSTEMS, INC. By: /s/ Paul Ashton By: /s/ Dan Myers \_\_\_\_\_ \_\_\_\_\_ Name: Dan Myers Name: Paul Ashton ----------Title: President, CEO Title: CEO -----\_\_\_\_\_

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# EXHIBITS

EXHIBIT 1.11A:	CDS EXISTING PATENT RIGHTS
EXHIBIT 1.11B:	EXCLUDED CDS PATENTS AND PATENT APPLICATIONS
EXHIBIT 1.15:	CDS PATENT COST-SHARING COUNTRIES
EXHIBIT 1.42:	EXCLUDED PRODUCT SPECIFICATIONS/DRAWINGS
EXHIBIT 1.87:	UKRF LICENSES
EXHIBIT 3.2:	INITIAL DEVELOPMENT PLAN
EXHIBIT 5.8.3:	TERMS FOR OPTION LICENSE AGREEMENT
EXHIBIT 11.5.1	TERMS FOR THE [*] LICENSE AGREEMENT

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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# CDS EXISTING PATENT RIGHTS

[\*]

[\*]-INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES AND EXCHANGE ACT OF 1934, AS AMENDED.

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# [\*]

EXHIBIT 1.42

# EXCLUDED PRODUCT SPECIFICATIONS/DRAWINGS

FIGURE 1 [\*] FIGURE 2

[\*]

# UKRF LICENSES

- A. License Agreement dated October 20, 1991, as amended August 10, 1993, relating to U.S. Patent No. 5,378,475 (Application No. 07/658,695)
- B. License Agreement dated September 9, 1997 relating to U.S. Patent Nos. 5,773,109 and 6,001,386 (Application No. 08/534,854)

# INITIAL DEVELOPMENT PLAN

[\*]

# EXHIBIT 5.8.3

# TERMS FOR OPTION LICENSE AGREEMENT

	Any terms not defined herein shall have those definitions set forth in the Collaboration Agreement
LICENSE	Alimera shall have a non-exclusive license under the CDS Technology (as in existence on the Option License Effective Date (as defined below), with the right to sublicense, to make, have made, use, import, sell, and offer for sale the Option Product in the Collaboration Field in the Territory. During the term of this option license, CDS shall not (a) grant a license to any Affiliate or Third Party under CDS' interest in the CDS Technology to make, have made, use, offer to sell, sell, or import such Option Product in the Collaboration Field in the Territory, and (b) itself use the CDS Technology to make, have made, use, offer to sell, sell, or import such Option Product in the Collaboration Field in the Territory. Alimera shall have an exclusive royalty-free license to use the "MEDIDUR" mark Controlled by CDS on or in connection with the Option Product marketed, distributed or sold pursuant to this license.
ROYALTIES	During the option license term, Alimera shall pay to CDS on a quarterly basis a royalty of [*] of Net Sales by Alimera or its Affiliates.
DILIGENCE	As provided in Section 4.3 of the Collaboration Agreement.
SUBLICENSES	Alimera shall have full rights to sublicense without consent, provided that such sublicense shall be consistent with the term of the option license. [*]
OWNERSHIP OF AND RIGHTS TO INVENTIONS	As provided in Section 5.4 of the Collaboration Agreement.
LIMITATION ON USE, RESERVATION OF RIGHTS BY CDS, AND NO GRANT OF OTHER TECHNOLOGY OR PATENT RIGHTS	As provided in Section 5.5, 5.6 and 5.7 of the Collaboration Agreement.

PATENT MAINTENANCE AND ENFORCEMENT	As provided for in Article 7 of the Collaboration Agreement. Neither Party is obligated to pay for patent costs or enforcement costs under this license as long as either the Collaboration Agreement or the [*] license pursuant to Section 11.5.1 of the Collaboration Agreement is in effect. If neither the Collaboration Agreement nor the [*] license pursuant to Section 11.5.1 of the Collaboration Agreement is in effect, then CDS shall have the primary control in filing, prosecution, maintenance and enforcement of CDS Patent Rights. The Parties [*] patent costs. Any amounts recovered as a result of any infringement action taken by the Parties hereunder shall be first applied, on a pro-rata basis, to reimburse each Party for its out-of-pocket expenses incurred in connection with such action and the remainder, if any, shall be divided appropriately [*].
REGULATORY	All regulatory filings and/or Approvals related to the Option Product that are subject of this license will be immediately transferred to Alimera and Alimera shall own all such filings and Approvals.
PATENT MARKING	As provided in Section 7.7 of the Collaboration Agreement.
INDEMNITY	As provided for in Article 10, except that CDS shall not be responsible for product liability claims as described in Section 10.5 arising based on acts or omissions after the Option License Effective Date except to the extent the claims are attributable to CDS' gross negligence or willful misconduct.
REPORTS	Alimera will provide to CDS a quarterly written account of the Net Sales of Option Products together with any relevant sublicense revenues and royalty payments.
TERM; TERMINATION	Commences upon Alimera's exercise of its rights pursuant to Section 5.8.3 under the Collaboration Agreement (the "Option License Effective Date") and expires upon the expiration or abandonment of the last Valid Claim included in the relevant CDS Patent Rights.
	Alimera may terminate the license at any time by giving CDS ninety (90) days written notice. CDS may terminate the license if Alimera: (a) fails to make any payment due under the license, unless Alimera makes such payments within sixty (60) days after receipt of written notice from CDS, or (b) commits a material breach of any other provision of the license, and such breach is not cured within ninety (90) days after receipt of written notice from CDS.

REPRESENTATIONS<br/>AND WARRANTIESAs provided in Article 9 of the Collaboration Agreement.CONFIDENTIALITY<br/>AND MISCELLANEOUSAs provided in Article 8 and Sections 12.1-12.8 and 12.10-12.13 of<br/>the Collaboration Agreement.

# EXHIBIT 11.5.1

# TERMS FOR THE [\*] LICENSE AGREEMENT

Any terms not defined herein shall have those definitions set forth in the Collaboration Agreement Alimera shall have a non-exclusive license under the CDS Technology (as in LICENSE existence on the License Effective Date (as defined below), with the right to sublicense, to make, have made, use, import, sell, and offer for sale the Product that CDS has abandoned pursuant to Section 11.5.1 of the Collaboration Agreement in the Collaboration Field in the Territory. During the term of the license, CDS shall not (a) grant a license to any Affiliate or Third Party under CDS' interest in the CDS Technology to make, have made, use, offer to sell, sell, or import such Product in the Collaboration Field in the Territory, and (b) itself use the CDS Technology to make, have made, use, offer to sell, sell, or import such Product in the Collaboration Field in the Territory. Alimera shall have an exclusive royalty-free license to use the "MEDIDUR" mark Controlled by CDS on or in connection with any Products marketed, distributed or sold pursuant to this license. During the license term, Alimera shall pay to CDS on a quarterly basis a royalty of ROYALTIES [\*] of Net Sales by Alimera or its Affiliates. DILIGENCE As provided in Section 4.3 of the Collaboration Agreement. SUBLICENSES and subcontracts Alimera shall have full rights to sublicense without consent, provided that such sublicense shall be consistent with the term of this license. [\*] CLINICAL IP/KNOW-CDS shall have transferred, or shall transfer, to Alimera copies of all HOW pre-clinical and clinical data that (1) relate to the Product that is the subject of this license, and (2) are owned or Controlled by CDS as of the License Effective Date. Alimera shall have the exclusive right to use such preclinical and clinical data to make, have made, use, import, sell, and offer for sale such Product in the Field in the Territory. As provided in Section 5.4 of the Collaboration Agreement. OWNERSHIP OF AND RIGHTS TO INVENTIONS As provided for in Article 7 of the Collaboration Agreement. Neither Party is PATENT obligated to pay for patent costs or enforcement costs under MAINTENANCE AND

ENFORCEMENT	this license as long as the Collaboration Agreement is in effect. Thereafter, CDS shall have the primary control in filing, prosecution, maintenance and enforcement of CDS Patent Rights. The Parties shall [*] patent costs. Any amounts recovered as a result of any infringement action taken by the Parties hereunder shall be first applied, on a pro-rata basis, to reimburse each Party for its out-of-pocket expenses incurred in connection with such action and the remainder, if any, shall be divided appropriately between the Parties [*].
PATENT MARKING	As provided in Section 7.7 of the Collaboration Agreement.
REGULATORY	Subject to applicable legal and regulatory requirements, all regulatory filings and/or Approvals related to the Product that is the subject of this license will be promptly transferred to Alimera and Alimera shall own all such filings and Approvals.
INDEMNITY	As provided for in Article 10, except that CDS shall not be responsible for product liability claims as described in Section 10.5 arising based on acts or omissions after the License Effective Date except to the extent the claims are attributable to CDS' gross negligence or willful misconduct.
REPORTS	Alimera will provide to CDS a quarterly written account of the Net Sales of the Products, together with any relevant sublicense revenues and royalty payments.
TERM; TERMINATION	Commences upon Alimera's exercise of its rights pursuant to Section 11.5.1 under the Collaboration Agreement (the "License Effective Date") and expires upon the expiration or abandonment of the last Valid Claim included in the relevant CDS Patent Rights.
	Alimera may terminate the license at any time by giving CDS ninety (90) days written notice. CDS may terminate the license if Alimera: (a) fails to make any payment due under the license, unless Alimera makes such payments within sixty (60) days after receipt of written notice from CDS, or (b) commits a material breach of any other provision of the license, and such breach is not cured within ninety (90) days after receipt of written notice from CDS.
REPRESENTATIONS AND WARRANTIES	As provided in Article 9 of the Collaboration Agreement.
CONFIDENTIALITY AND MISCELLANEOUS	As provided in Article 8 and Sections 12.1–12.8 and 12.10–12.13 of the Collaboration Agreement.

#### AMENDMENT NO. 1 TO

# COLLABORATION AGREEMENT

# BY AND BETWEEN

# CONTROL DELIVERY SYSTEMS, INC.

### AND

# ALIMERA SCIENCES, INC.

This Amendment No. 1 to the Collaboration Agreement by and between Control Delivery Systems, Inc. and Alimera Sciences, Inc. dated as of February 11, 2005 (the "Agreement") is made as of February 23, 2005, and modifies certain terms of the Agreement.

The undersigned Parties hereby agree as follows:

1. The fourth sentence of Section 3.2.4 (a) (i) of the Agreement is amended to read as follows:

As soon as practicable, CDS shall submit to the FDA a letter in form and substance satisfactory to both Parties authorizing a person designated by Alimera and reasonably acceptable to CDS (initially [\*]) to communicate directly with the FDA regarding the CDS IND.

2. Section 6.2 of the Agreement is amended to read as follows:

6.2 Milestone Payments. Alimera shall make an additional payment of \$750,000 to CDS ("Milestone Payment"), which shall be disbursed as follows:

- (a) [\*] upon [\*]
- (b) [\*] upon [\*]
- (c) [\*] when [\*]
- (d) [\*] upon [\*] and
- (e) [\*] and any unpaid amounts from (a) through (d) above upon the [\*]

3. Except as otherwise set forth in this Amendment No. 1, the terms of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused this instrument to be executed by their duly authorized representatives.

CONTROL DELIVERY SYSTEMS, INC.

By: /s/ Paul Ashton

Name: Paul Ashton

Title: Chief Executive Officer \_\_\_\_\_

ALIMERA SCIENCES, INC. : /s/ Paul Ashton By: /s/ Dan Myers me: Paul Ashton Name: Dan Myers cle: Chief Executive Officer Title: President, CEO -----\_\_\_\_\_ ----- AMENDMENT NO. 2 TO

# COLLABORATION AGREEMENT

### BY AND BETWEEN

# CONTROL DELIVERY SYSTEMS, INC.

### AND

# ALIMERA SCIENCES, INC.

This Amendment No. 2 to the Collaboration Agreement by and between Control Delivery Systems, Inc. and Alimera Sciences, Inc. dated as of February 11, 2005 and amended on February 23, 2005 (the "Agreement") is made as of May 11, 2005, and modifies certain terms of the Agreement.

The undersigned Parties hereby agree as follows:

1. Section 3.2.3 of the Agreement is hereby deleted in its entirety and the following is substituted in place thereof:

3.2.3. Allocation of Responsibility for Development Activities. The Parties acknowledge and agree that each Development Plan shall allocate primary responsibility for the various activities (and any related or ancillary activities) listed below to be performed by the responsible Party as follows:

Activity		Responsible Party
 A.	Preclinical research and development, including Product design,formulation, preclinical safety studies and in vivo pharmacology studies	CDS
в.	Technology transfer as described in Section 3.11	CDS
С.	Phase I, Phase I/II, Phase II and Phase III Clinical Trials, as needed to procure data necessary for the acceptance of filing of an NDA	Alimera
D.	Preparation, filing and maintenance of regulatory filings	Alimera
E.	Manufacturing for Clinical Supply Requirements	CDS
F.	Filing, prosecution and maintenance of CDS Patent Rights (subject to Alimera's rights in Article 7)	CDS

For clarification, commercial manufacturing is Commercialization for which Alimera has primary responsibility as set forth in greater detail in Article 4. 2. Section 3.2.4 (a) of the Agreement is hereby deleted in its entirety and the following is substituted in place thereof:

### 3.2.4 Regulatory Approvals.

(a) Regulatory Filings. Unless otherwise agreed by the Parties, Alimera shall be responsible for all U.S. and non-U.S. regulatory matters, including filing an IND and NDA for the first Product, provided that no regulatory filings by Alimera shall include any Pre-Existing Clinical IP. Alimera shall be responsible for obtaining Approvals and for subsequent maintenance of Approvals. For all regulatory filings made in the name of Alimera, Alimera shall have the primary authority and responsibility, with input from CDS, for submitting supplements, communications, annual reports, adverse event reports, manufacturing changes, supplier designations and other related filings, and for communicating with FDA. The Party responsible for submitting regulatory filings (the "Regulatory Submission Party") shall provide the other Party (the "Regulatory Non-Submission Party") with copies of all substantive submissions to (which may be in draft form), and all correspondences from, the FDA or other regulatory authorities. The Regulatory Non-Submission Party may provide comments regarding such submission prior to such planned submission, and the Regulatory Submission Party shall consider in good faith incorporating into the planned submission any such comments. The Regulatory Non-Submission Party shall supply Know-How necessary to obtain Approvals for each Product.

3. Section 6.2 of the Agreement is hereby deleted in its entirety and the following is substituted in place thereof:

 $\,$  6.2 Milestone Payments. Alimera shall make an additional payment of [\*] to CDS ("Milestone Payment"), which shall be disbursed as follows:

- (a) [\*] upon [\*]
- (b) [\*] upon execution of this Amendment No. 2; and
- (c) [\*] when a [\*]

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4. Except as otherwise set forth in this Amendment No. 2, the terms of the Agreement shall remain in full force and effect.

ATTMEDA COTENCES INC

IN WITNESS WHEREOF, the parties have caused this instrument to be executed by their duly authorized representatives.

CONTROL DELIVERY SISTEMS, INC.	ALIMERA SCIENCES, INC.
/s/ Michael J. Soja By:	/s/ Daniel H. White By:
Michael J. Soja Name:	Daniel H. White Name:
VP Finance	VP Finance and Corporate Development
Title:	Title:
[*]-INDICATES MATERIAL THAT HAS	BEEN OMITTED AND FOR WHICH CONFIDENTIAL

# COMMERCIAL SUBLEASE

THIS COMMERCIAL SUBLEASE (the "Sublease") is made this 6th day of April, 2005 (the "Commencement Date"), by and between Exergen Corporation, a Massachusetts corporation having an address at 400 Pleasant Street, Watertown, Massachusetts (the "Landlord"), and Control Delivery Systems, Inc., a Delaware corporation, having its principal place of business at 400 Pleasant Street, Watertown, Massachusetts (the "Subtenant").

### WITNESSETH:

WHEREAS, by Commercial Building Lease dated as of the date hereof between FHP, LLC, a Massachusetts limited liability company, as lessor (the "Overlandlord"), and Landlord as lessee thereunder (the "Original Sublease"), Overlandlord leased to Landlord the premises, together with the right to use all sidewalks, parking areas, easements, rights of way and other means of access to and from public ways and adjoining properties, being the entire premises now known and numbered as 396-400 Pleasant Street, Watertown, Massachusetts (the "Property"); and

WHEREAS, Subtenant desires to sublease from Landlord and Landlord desires to sublease to Subtenant, a portion of the Premises as shown on Exhibit A attached hereto and described below on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

### ARTICLE I

### DEMISE

Section 1. Landlord hereby leases the space shown on Exhibit A attached hereto consisting of 13,411 square feet exclusive use space (the "Subleased Premises"), together with the right to use in common with others entitled thereto the approximately 1,038 square feet of common area space shown on Exhibit A (the "Common Area") and other common walkways, hallways, driveways and similar areas necessary for access to the Subleased Premises, situated in or about the building (the "Building") located at the Property to Subtenant and Subtenant hereby leases and takes the Subleased Premises from Landlord upon the terms, provisions and conditions in this Sublease contained, and subject to any easements, restrictions and conditions of record and all laws and ordinances applicable to the Subleased Premises.

Section 2. Subtenant acknowledges that Subtenant owned and occupied the Building prior to the sale of the Building to Landlord by Subtenant on the date hereof. As a result, Subtenant is thoroughly familiar with the condition of the Building and agrees that it is leasing the Subleased Premises "as is" with no representations or warranties by Landlord, including,

without limitation, any representations or warranties as to habitability or fitness for a particular purpose.

### ARTICLE II

#### TERM

Section 1. The term of this Sublease shall commence on the Commencement Date and shall continue for a period of eighteen (18) months, unless sooner terminated or extended as herein provided (the "Term").

Section 2. Landlord and Subtenant each shall have an option to extend the Term for eighteen (18) months (the "Extension Period"), provided that the party seeking to exercise such option shall not be in default under any of the material terms of this Sublease at the time of the exercise. If either Landlord or Subtenant elects to exercise this option, it shall do so by giving written notice of such election to the other no later than six (6) months prior to the end of the original Term. The Extension Period shall be upon the same terms and conditions of this Sublease, except that during the Extension Period, Subtenant shall pay Annual Base Rent equal to \$23.00 per square foot for the Subleased Premises and for Subtenant's Proportionate Share (as defined in Article III, Section 3 below) of the Common Area.

#### ARTICLE III

#### RENT

Section 1. Subtenant shall pay without demand, setoff or deduction as rent at such place as Landlord from time to time may direct, annual base rent (the "Annual Base Rent") equal to \$22.00 per square foot for the Subleased Premises and for Subtenant's Proportionate Share (as defined in Article III, Section 3 below) of the Common Area. As of the Commencement Date, the Subleased Premises constitute 13,411 square feet and Subtenant's Proportionate Share of the Common Area constitutes 386 square feet. Therefore, Subtenant shall pay as Annual Base Rent the amount of Three Hundred Three Thousand Five Hundred Thirty Four Dollars (\$303,534) in equal monthly installments of Twenty Five Thousand Two Hundred Ninety Four Dollars (\$25,294) on the first day of each calendar month; provided, however, that the first calendar month's rent shall be paid on the Commencement Date. If the Commencement Date falls on other than the first day of a calendar month or if the Term ends on other than the last day of a calendar month, the Annual Base Rent shall be prorated for the month in which the Term commences or ends, as the case may be.

Section 2. During the Term, in addition to Annual Base Rent, Subtenant agrees to pay to Landlord, as additional rent (the "Additional Rent"), Subtenant's Proportionate Share (as defined in Article III, Section 3 below) of all Taxes (as defined in Article III, Section 4 below) and Operating Expenses (as defined in Article III, Section 5 below) that accrue during the Term and Subtenant's portion of Shared Utilities (as described in Article V, Sections 2 and 3 below) that accrue during the Term. On the Commencement Date and thirty (30) days prior to the beginning

of each calendar year during the Term (including, if applicable, the Extension Period), Landlord shall submit an estimate of the Additional Rent for the ensuing calendar year and Subtenant shall pay Landlord such estimated amount of Additional Rent in monthly installments on the first day of each calendar month during the Term. At the end of each calendar year during the Term (including, if applicable, the Extension Period) and at the termination of the Sublease, as soon as Landlord can determine the actual amount of Additional Rent owed by Subtenant for the preceding year (or, if applicable, portion thereof), Landlord shall give Subtenant written notice of such amount (the "Additional Rent Statement"). The Additional Rent Statement shall include an itemized statement showing in reasonable detail the actual Taxes, Operating Expenses, and Shared Utilities for the relevant period broken down by component expenses. Upon request by Subtenant, Landlord also shall provide appropriate supporting documentation.

If the actual amount of Additional Rent owed by Subtenant exceeds the estimated amount paid by Subtenant, Subtenant shall pay such excess to Landlord within ten (10) days of receipt by Subtenant of the Additional Rent Statement or the end of the Dispute Period (as defined below). If the estimated amount of Additional Rent paid by Subtenant exceeded the actual amount owed by Subtenant, Landlord shall pay such excess to Subtenant within ten (10) days of receipt by Subtenant of the Additional Rent paid Berne Statement.

If Subtenant disputes the accuracy of the Additional Rent Statement, Subtenant shall have thirty (30) days after receiving the Additional Rent Statement, or such longer time as may be necessary, to audit Landlord's books and records concerning the Additional Rent Statement at a mutually convenient time at Landlord's offices. The books and records shall be kept in accord with generally accepted accounting principles consistently applied. If the parties cannot resolve the dispute within thirty (30) days after completion of the audit (the "Dispute Period"), Subtenant shall still pay the amount shown owing within ten (10) days of the end of the Dispute Period and Subtenant, in its sole discretion, may commence alternative dispute resolution procedures or submit the matter to a court of competent jurisdiction. Any such audit shall be conducted at Subtenant's sole cost and expense. If a court, arbitrator or mediator determines that the Additional Rent Statement overstated the Additional Rent by three percent (3%) or more, Subtenant may recover the amount it spent on the audit, the amount it paid in excess of the correct Additional Rent, and its reasonable attorneys' fees and costs associated with the dispute. If a court, arbitrator or mediator determines that the Additional Rent Statement overstated the Additional Rent, but by an amount less than three percent (3%), then Subtenant may recover only the amount it paid in excess of the correct Additional Rent. If Subtenant does not commence alternative dispute resolution procedures or submit the matter to a court of competent jurisdiction within sixty (60) days after the end of the Dispute Period, then the Additional Rent Statement shall be conclusive and final.

The provisions of this Article III, Section 2 shall survive expiration or termination of the Sublease.

Section 3. For all purposes of this Sublease, "Subtenant's Proportionate Share" of the Building on and as of the Commencement Date shall be 37.19%. Subtenant's Proportionate Share is calculated as follows:

sq. ft. of Subleased Premises

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(sq. ft. of Building - sq. ft. of Common Area)

In the event that the square footage of any pertinent area changes for any reason, Subtenant's Proportionate Share shall be automatically recalculated in accordance with the above equation and using the same measurement techniques and standards originally employed.

Section 4. "Taxes" shall mean any and all governmental impositions and taxes imposed upon the Building and/or the Property, including any fire service or other charges for municipal services, and all betterment assessments, as well as all ad valorem, license or other taxes imposed upon the Building and/or the Property and/or imposed upon Landlord by reason of its ownership thereof or this Sublease; provided, however, that "Taxes" shall not include (i) federal, state, or local income taxes, (ii) franchise, gift, transfer, excise, capital stock, estate, succession, or inheritance taxes, (iii) penalties or interest for late payment of Taxes, or (iv) the portion of Taxes that is allocable to any capital improvements made after the Commencement Date expect to the extent the improvements benefit all tenants or at least benefit Subtenant. If at any time during the Term the methods of taxation of real estate prevailing on the Commencement Date shall be altered so that in lieu of, in addition to, or as a substitute for, the whole or any part of the Taxes, there shall be levied, assessed or imposed (x) a tax, assessment, levy, imposition or charge, wholly or partially as capital levy or otherwise, on the rents received therefrom, (y) a tax, assessment, levy, imposition or charge measured by or based in whole or in part upon the Subleased Premises and imposed upon Landlord, or (z) a tax license fee or the like measured by the rents payable from Subtenant to Landlord, then all such taxes, assessments, levies, impositions, or charges, or the part thereof so measured or based, shall be deemed to be included within the term "Taxes" for the purposes hereof. In the event of a betterment assessment, Landlord shall pay in accordance with the longest payment option offered

Section 5. "Operating Expenses" shall mean any expenses, costs and disbursements invoiced to Landlord by an unaffiliated entity (except as agreed to by Subtenant) in connection with the maintenance, operation and repair of all or any part of the Building, including the Common Area and the parking and other common areas outside the Building on the Property (in connection with which Operating Expenses shall include snow removal and landscaping). Landlord agrees to maintain, operate and repair the Building and Property to a standard consistent with Subtenant's former ownership thereof. "Operating Expenses" shall not include (i) costs incurred due to maintenance, operation and repair of the Building and/or Property to a standard in excess of Subtenant's former ownership thereof, (ii) expenses, costs, and disbursements incurred in connection with Shared Utilities (as defined in Article V, Section 2 below), (iii) Taxes (as defined in Article III, Section 4 above), (iv) leasing commissions, costs,

disbursements, and other expenses incurred for leasing, renovating, or improving space for Landlord or other tenants, (v) costs incurred by Landlord in discharging its obligations under Article XXV, (vi) costs (including permit, license, and inspection fees) incurred in renovating, improving, decorating, painting, or redecorating vacant space or space for Landlord or other tenants, (vii) costs incurred by Landlord for alterations that are considered capital improvements and replacements under generally accepted accounting principles consistently applied, (viii) depreciation and amortization on the Building except as expressly permitted elsewhere in the Sublease, (ix) costs of a capital nature including capital improvements, capital repairs, capital equipment, and capital tools, as determined under generally accepted accounting principles consistently applied, (x) costs incurred because Landlord or another tenant violated the terms of any lease, (xi) interest on debt or amortization payments on mortgages or deeds of trust or any other debt for borrowed money, (xii) rentals and other related expenses incurred in leasing air conditioning systems or other equipment ordinarily considered to be of a capital nature, but normal maintenance shall be included, (xiii) items and services for which Subtenant reimburses Landlord or pays third parties or that Landlord provides selectively to one or more tenants of the Building other than Subtenant without reimbursement, (xiv) advertising and promotional expenditures, (xv) repairs or other work needed because of fire, windstorm, or other casualty or cause insured against by Landlord or to the extent Landlord's insurance required under this Sublease would have provided insurance, whichever is the greater coverage, (xvi) nonrecurring costs incurred to remedy structural defects in original construction materials or installations, (xvii) any costs, fines, or penalties incurred because Landlord violated any governmental rule or authority, (xviii) costs incurred to test, survey, cleanup, contain, abate, remove, or otherwise remedy Hazardous Material (as defined in Article X, Section 2 below) in, on, or under the Property unless and to the extent that the Hazardous Material was in, on, or under the Property as a result of Subtenant's negligence or wrongful acts, (xix) costs incurred to comply with the Americans with Disabilities Act except to the extent compliance is required because of amendment(s) to such law, which amendment(s) became effective after the Commencement Date, (xx) costs for sculpture, paintings, or other art, and (xxi) other expenses that under generally accepted accounting principles consistently applied would not be considered normal maintenance, operation or repair expenses.

Section 6. Subtenant agrees to make monthly Annual Base Rent installments, Additional Rent payments, Security Payments (as described in Article XXIII, Section 1 below) and, if applicable, Swap Payment repayments (as described in Article XXVI, Section 1 below) to Landlord by automatic electronic transfer. If Subtenant does not pay the Annual Base Rent, Additional Rent or any other charges due hereunder within five (5) days of when due, Subtenant shall pay Landlord a late charge equal to five percent (5%) of such payment; and, if such payment shall be made more than ten (10) days after such five (5) day grace period, Subtenant shall in addition pay Landlord interest on such payment at the rate of one percent (1%) per month from the date due until the date paid.

#### ARTICLE IV

USE OF THE SUBLEASED PREMISES

Section 1. Subtenant shall use the Subleased Premises solely and exclusively pursuant to the terms of this Sublease for office, research and development, storage, or other activities incidental to and accessory to Subtenant's business, and for no other purposes whatsoever without the written consent of the Landlord.

Section 2. Subtenant shall comply with all present and future laws, rules, regulations, ordinances, requirements, and orders of public authorities relating to Subtenant's use and occupancy of the Subleased Premises, including, without limitation, building and zoning laws, requirements of Board of Health and requirements of any other federal, state or local agencies having jurisdiction of the Subleased Premises and the Building, including, without limitation, any structural change required to be performed by Subtenant by any of the same. Subtenant shall furthermore comply with all reasonable requirements of Landlord's insurance carrier, and any Board of Fire Underwriters, or similar bodies.

Section 3. Subtenant shall be entitled to use Subtenant's Proportionate Share of the parking areas on the Property as designated by Landlord.

#### ARTICLE V

### UTILITIES

Section 1. Subtenant shall pay all charges for utilities used exclusively in the Subleased Premises (i.e., those utilities used in the Subleased Premises that are not "Shared Utilities," as defined in Article V, Section 2 below) whether such charges shall be made by a quasi-public or private utility company or by a governmental authority or subdivision or department thereof. Subtenant shall cause each such utility service to be separately metered to itself in its name and shall be fully responsible for all costs in connection therewith. If Landlord shall pay any of such charges on behalf of Subtenant, Subtenant shall reimburse Landlord upon demand. Landlord shall not be responsible to Subtenant for the failure or interruption of any such utilities unless such failure or interruption is caused by the gross negligence or willful misconduct of Landlord or his agents.

Section 2. "Shared Utilities" shall mean utilities serving the Building as a whole (e.g., gas, electricity and water) and the maintenance and repair of related common mechanical systems and equipment (e.g., HVAC and electrical systems). Landlord and Subtenant shall share responsibility for the expenses, costs, and disbursements to third parties incurred in connection with Shared Utilities. All Shared Utilities shall remain in Landlord's name and Landlord shall pay the utility suppliers. Subtenant shall reimburse Landlord for its portion of such expenses, costs, and disbursements as set forth in Article V, Section 3. Landlord shall not be responsible to Subtenant for the failure or interruption of any Shared Utilities unless such failure or interruption is caused by the gross negligence or willful misconduct of Landlord or his agents. Beginning promptly after the Commencement Date, and sooner if feasible, Landlord shall retain and pay an energy consultant to develop a cost reduction strategy for Shared Utilities and a contractor to

implement the energy consultant's recommended improvements. The parties estimate that the total cost of such work will be approximately \$40,000 ("Program Costs"). In no event shall Program Costs exceed \$50,000.

Section 3. Subtenant's portion of expenses, costs, and disbursements to third parties incurred in connection with Shared Utilities shall be determined as set forth below. If at any time during the Term or the Extension Period, if any, the cost of electricity or gas changes from the cost of such utilities during the Reference Year (as defined below), Landlord and Subtenant agree to make mutually acceptable appropriate changes to Exhibit B to preserve the intended economics of this Article V, Section 3.

- (a) First Six Months of Term.
  - (1) During the first six months of the Term, Subtenant shall make monthly estimated payments to Landlord for Shared Utilities ("Estimated Payments"). Each Estimated Payment shall be equal to Subtenant's costs in the same calendar month as set forth in Exhibit B. Exhibit B shows the amounts incurred by Subtenant and Landlord respectively at their former properties for the period December 1, 2003 through November 30, 2004 (the "Reference Year"). By way of clarification, Subtenant's Estimated Payment for May during the first six months of the Term would be \$18,295, which is the corresponding amount for May in the Reference Year.
  - (2) Within fifteen (15) days of the end of the first six months of the Term, Landlord shall determine the actual amount spent for Shared Utilities (the "Actual Amount"). The Actual Amount then shall be compared to the total Estimated Payments made by Subtenant during the first six months of the Term plus Landlord's total costs at his former property during the corresponding six calendar months in the Reference Year as shown in Exhibit B (together, the "Reference Amount"). By way of clarification, if the first six months of the Term are May 2005 through October 2005, then the Reference Amount shall be \$165,903 (total costs incurred by both Landlord and Subtenant during the months May 2004 through October 2004 at their former properties).
    - (i) If the Actual Amount is less than the Reference Amount, the difference shall be deemed "Savings." Savings shall first be applied to reimburse Landlord for the Program Costs. If a balance remains after such reimbursement, Landlord shall pay Subtenant fifty percent (50%) of such balance.
    - (ii) If the Actual Amount is greater than the Reference Amount, the difference shall be deemed "Excess." In the event of an Excess, Subtenant shall pay Landlord fifty percent (50%) of the Excess.

- (b) Second Six Months of Term.
  - (1) During the second six months of the Term, Subtenant shall make monthly Estimated Payments to Landlord that are adjusted to reflect the percentage of Savings realized by Subtenant in the first six months of the Term ("Adjusted Estimate Payments"). Each Adjusted Estimated Payment shall be equal to Subtenant's costs in the same calendar month as set forth in Exhibit B reduced by a fraction the numerator of which is the Savings from the first six months of the Term divided by two, and the denominator of which is the total Estimated Payments made by Subtenant during the first six months of the Term.
  - (2) Within fifteen (15) days of the end of the second six months of the Term, Landlord shall determine the Actual Amount for such period and compare it to the Reference Amount for such period.
    - (i) If the Actual Amount is less than the Reference Amount, there shall be Savings for the second six months of the Term. Landlord shall be entitled to fifty percent (50%) of such Savings. Landlord shall subtract the following from the other fifty percent (50%) and, if a balance remains, shall pay such balance to Subtenant: (x) any unpaid Program Costs; and (y) the difference between Subtenant's Estimated Payments for the second six months of the Term and the Adjusted Estimated Payments for the same period.
    - (ii) If the Actual Amount is greater than the Reference Amount such that there is an Excess for the second six months of the Term, Subtenant shall pay Landlord fifty percent (50%) of such Excess.

(c) Third Six Months of Term.

Determined using the methodology for the second six months of the Term.

- (d) Extension Period.
  - (1) If there is an Extension Period, Subtenant shall make monthly Estimated Payments to Landlord.
  - (2) Within fifteen (15) days of the end of each six months of the Extension Period, Landlord shall determine the actual amount spent for Shared Utilities during the applicable six month period and deduct Landlord's total costs at his former property during the corresponding six calendar months in the Reference Year as shown in Exhibit B (the "Extension Actual Amount"). The Extension Actual Amount then shall be compared to the total Estimated

Payments made by Subtenant during the applicable six month period (the "Extension Reference Amount").

- (i) If the Extension Actual Amount is less than the Extension Reference Amount such that there are Savings for the applicable six month period, Landlord pay Subtenant one hundred percent (100%) of such Savings.
- (ii) If the Extension Actual Amount is greater than the Extension Reference Amount such that there is an Excess for the applicable six month period, Subtenant shall pay Landlord one hundred percent (100%) of such Excess.

### ARTICLE VI

#### REPAIRS

Section 1. Subject to the other terms of this Sublease, including Article V, Section 2 and those terms relating to fire or other casualty, Landlord at its expense shall keep the roof, structure, and mechanical systems in or on the Building in good order and repair; provided, however, that Subtenant shall reimburse Landlord for the reasonable cost of such repairs to the extent the repairs are caused by the negligence or misconduct of Subtenant, its employees, contractors, agents and guests, and to the extent that the cost of the repairs are not covered by insurance that Landlord is required to maintain under this Sublease. Notwithstanding anything to the contrary contained in this Sublease, Subtenant shall be responsible, at its sole expense, for keeping any mechanical systems that exclusively serve the Subleased Premises in good order and repair.

Section 2. Throughout the Term, Subtenant agrees to maintain the Subleased Premises and all additions and improvements made upon them in good order and repair, reasonable wear and tear and damage by fire or other casualty excepted.

#### ARTICLE VII

# RULES, REGULATIONS AND SIGNS

Section 1. Subtenant shall comply with all reasonable rules and regulations from time to time promulgated in writing by Landlord, provided that the same are applicable to all Subtenants and occupants of the Building and do not conflict with any right expressly granted to Subtenant in this Sublease. Without consent from Landlord, Subtenant shall not: (a) keep or permit any outside display or sales, nor place, maintain or permit any signs, placards, lettering, awnings, aerials, flagpoles, decorations or the like or other installations upon the exterior or roof of the Building, except for (i) a sign on or near the front entrance of the Building indicating the location

of the entrance to the Subleased Premises and (ii) a sign on or near the entrance to the Subleased Premises indicating the same; or (b) make any holes in or outside the Building, except as may be necessary for installation or removal of any approved signs or approved alterations or trade fixtures and equipment (Subtenant hereby agreeing that upon vacating the Subleased Premises it shall repair any and all damage caused by any such installation or removals).

#### ARTICLE VIII

### ALTERATIONS BY SUBTENANT

Section 1. Subtenant shall not make any alterations costing in excess of \$50,000 in the Subleased Premises without the prior written consent of Landlord, which consent shall not be unreasonably withheld or delayed. Prior to the commencement of any construction within the Subleased Premises, Subtenant shall submit plans and specifications to Landlord for its approval. All work performed by Subtenant shall be done in a good and workmanlike manner and in full compliance with all laws and ordinances, and using materials of quality at least equal to those employed in the rest of the Building. Upon completion of the work, Subtenant shall deliver to Landlord sworn statements and lien waivers evidencing that such work has been fully paid for. Subtenant shall indemnify and hold Landlord harmless from all claims, liabilities and expenses (including reasonable attorneys' fees) in connection with such work, including any mechanic liens, and shall cause all such mechanic liens to be discharged, bonded or insured over in a manner satisfactory to Landlord.

# ARTICLE IX

# COVENANTS OF SUBTENANT AND LANDLORD

Section 1. Subtenant shall throughout the Term hereof maintain the Subleased Premises in safe condition and repair, reasonable wear and tear and damage by fire or other casualty excepted, free from rubbish, dirt, refuse, or garbage; store all trash and garbage in approved receptacles within the Subleased Premises; handle all delivery and receiving of merchandise, supplies and other materials to and from the Subleased Premises through service areas provided for such use, if any; use the Common Area and other common areas in a proper manner and with due regard to the rights of others; notify Landlord promptly after the same shall come to the attention of Subtenant of the need for any repairs or replacements to the Building.

Section 2. Subtenant shall not during the Term hereof injure, overload or deface the Subleased Premises or the Building, nor permit nor suffer any use of the Subleased Premises, nor make any use of the Building or of the Subleased Premises, that will be improper, offensive, or contrary to law, or liable to invalidate any insurance, whether against risks of loss to persons or property, or otherwise, or which will be injurious to any person or property or which will constitute any waste or nuisance; and Subtenant shall pay any increase or extra premium payable for such insurance premiums resulting from any act done by Subtenant, or any other increase in insurance premiums resulting from non-compliance of its obligations under this Sublease. The statement of the insurer shall be conclusive, as to the cause of such increased or extra premium, unless

Subtenant shall establish to Landlord's reasonable satisfaction that Subtenant is not responsible for such increased or extra premium.

Section 3. To a standard consistent with Subtenant's former ownership and occupancy of the Property, Landlord shall during the Term ensure the provision of gas, electricity, water, HVAC service, and other such utilities, and landscaping, plowing, maintenance of the Common Area and other common areas, and similar services to and for the benefit of the Subleased Premises.

### ARTICLE X

# ENVIRONMENTAL MATTERS

Section 1. Subtenant shall not violate and shall promptly remedy or correct any violations by it of any federal, state or local laws, rules and regulations now or hereafter in effect with respect to Hazardous Material, as defined below, introduced to the Subleased Premises. Subtenant shall not use all or any portion of the Subleased Premises for the generation, storage, treatment, use or disposal of any Hazardous Material except in compliance with all applicable laws. Without limitation, express or implied, upon any other requirements of this Sublease, Subtenant shall pay all such sums and take all such actions as may be required to avoid or discharge the imposition of any lien on the Subleased Premises resulting from Subtenant's violation of Massachusetts General Laws, Chapter 21E, Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. Section 9601 et seq., or any other federal, state, local or other statute, law, ordinance, code, rule, regulation, order or decree regulating, relating to or imposing liability or standards of conduct concerning any Hazardous Material, and Subtenant shall indemnify and save harmless Landlord and Landlord's mortgagee from any and all reasonable losses, claims, liabilities and expenses, including, without limitation, reasonable attorneys' fees incurred or suffered by Landlord by virtue of Subtenant's violation of the provisions thereof as applied to the Subleased Premises. The provisions of this Article X, Section 1 shall survive the termination of this Sublease.

Section 2. For purposes of this Sublease, "Hazardous Material" means and includes any hazardous substance or any pollutant or contaminant defined as such in (or for purposes of) the federal, state, or local statute, law, ordinance, code, rule, regulation, order, or decree regulating, relating to, or imposing liability or standards of conduct concerning, any hazardous, toxic or dangerous waste, substance or material, as may now or at any time in the future be in effect, or any other hazardous, toxic or dangerous waste, substance, or material.

### ARTICLE XI

# LANDLORD'S ENTRY

Section 1. Landlord shall have the right to enter upon the Subleased Premises at all reasonable business hours upon reasonable notice (and at any time in case of an emergency) for the purpose of inspecting or exhibiting the same, or for the purpose of making repairs to the

Subleased Premises, or for any other purpose or purposes contemplated in this Sublease; provided, however, that none of the same shall be construed to impose upon Landlord any obligation or liability whatsoever for the care, supervision or repair of the Subleased Premises other than as expressly provided in this Sublease; and provided further, that, Landlord must be accompanied by an employee of Subtenant during each such entry (except in the case of an emergency as discussed below), shall abide by all safety and other rules and regulations of Subtenant, and agrees to hold in confidence and not use for any purpose any confidential or proprietary information of Subtenant received or observed during such entry. Landlord shall not, by reason of any inspection, be deemed to have received notice of any condition with respect to which Landlord is obligated to take any action under this Sublease. If Subtenant or its employees shall not be present to permit entry into said Subleased Premises and if at any time, due to emergency, an entry therein shall be necessary, Landlord or its agents may enter the Subleased Premises, forcibly, if necessary, to prevent injury to persons or damage to property without in any way rendering Landlord or its agents liable therefor or without affecting Subtenant's obligations contained in this Sublease. Landlord shall use all reasonable efforts to minimize any material inconvenience to Subtenant in exercising its rights hereunder.

# ARTICLE XII

#### INDEMNIFICATION

Section 1. To the fullest extent permitted by law, Subtenant agrees to indemnify and save Landlord harmless against any and all bodily and personal injury, loss, claim or damage to any person or property while on the Subleased Premises, and from and against all bodily and personal injury, loss, claim or damage to any person or property anywhere in the Building or on the Property caused by any wrongful act or omission or the negligence of Subtenant or of Subtenant's employees, agents, licensees, invitees or any other person for whom Subtenant is responsible, or caused by a default in the proper performance of Subtenant's obligation under the terms of this Sublease; provided, however, that Subtenant shall have no such indemnification obligations to the extent that any such injury, loss, claim or damage is caused by the wrongful act or omission or the negligence of Landlord, or of Landlord's employees, agents, licensees, invitees or any other person for whom Landlord is responsible, or caused by a default in the proper performance of this Sublease.

Section 2. To the fullest extent permitted by law, Landlord agrees to indemnify and save Subtenant harmless against any and all bodily and personal injury, loss, claim or damage to any person or property while on the Subleased Premises, and from and against all bodily and personal injury, loss, claim or damage to any person or property anywhere in the Building or on the Property caused by any wrongful act or omission or the negligence of Landlord or of Landlord's employees, agents, licensees, invitees or any other person for whom Landlord is responsible, or caused by a default in the proper performance of Landlord's obligation under the terms of this Sublease; provided, however, that Landlord shall have no such indemnification obligation to the extent that any such injury, loss, claim or damage is caused by the wrongful act or omission or the negligence of Subtenant, or of Subtenant's employees, agents, licensees, invitees or any other person for whom Subtenant is responsible, or caused by a default in the proper performance of Subtenant's obligation

# ARTICLE XIII

### SURRENDER

Section 1. At the expiration or prior termination of the Sublease, Subtenant shall surrender the Subleased Premises in good condition, reasonable wear and tear and damage by fire or other casualty excepted.

Section 2. All personal property and trade fixtures owned by Subtenant that can be removed without substantial physical injury to the Subleased Premises shall remain the property of Subtenant and shall be removed by Subtenant no later than the expiration or termination of the Sublease; provided, however, that if Subtenant is in default under this Article XIII, Section 2 or if any such property shall not be removed by the expiration or termination of this Sublease, such property shall, at the express written election of Landlord, be deemed to have become Landlord's property. Furthermore, in such event, Landlord may dispose of any of Subtenant's property not so removed at Subtenant's risk and expense. Subtenant shall repair any and all damage caused by the removal of Subtenant's personal property and trade fixtures.

### ARTICLE XIV

# INSURANCE

Section 1. During the Term, Subtenant shall maintain in full force and effect the following insurance, written by one or more insurance companies licensed to do business in the Commonwealth of Massachusetts having a Best rating of A or better, class VIII or better:

A. Workmen's compensation insurance covering all employees, and if Subtenant shall contract with any independent contractor for the furnishing of labor, materials or services to Subtenant, Subtenant shall require such independent contractor to maintain workmen's compensation insurance covering all its employees and all the employees of any subcontractors. Subtenant shall also maintain employers liability insurance having limits of not less than \$1,000,000.

B. Property insurance with standard extended coverage in an amount of not less than one hundred percent (100%) of the full sound insurable value of all of Subtenant's property and, if the Subleased Premises shall be sprinkled, sprinkler insurance in an amount of not less than one hundred percent (100%) of the full sound insurable value thereof. Said coverage shall include explosion and boiler insurance if appropriate.

C. Commercial general liability insurance with limits of \$2,000,000 as provided in the comprehensive general liability forms with contractual liability endorsements attached, in companies qualified to do business in the Commonwealth of Massachusetts, insuring against injury to persons and damage to property as herein provided, naming Landlord and Landlord's

Mortgagee as additional insureds thereunder. Such insurance may be carried by Subtenant under a blanket or umbrella coverage.

D. Comprehensive automobile liability insurance covering all owned, non-owned and hired vehicles, with limits of not less than \$1,000,000 combined single limit for personal injury and property damage.

Section 2. During the Term, Landlord shall maintain in full force and effect the following insurance, written by one or more insurance companies licensed to do business in the Commonwealth of Massachusetts having a Best rating of A or better, class VIII or better:

A. Landlord shall, throughout the term of this Sublease, keep the Building and all other improvements on the Property insured pursuant to one or more policies of property insurance written on an "all risk" of physical loss or damage basis in such amounts as would be equal to one hundred percent (100%) replacement cost of the Building and all other improvements on the Property, as is necessary to avoid co-insurance.

B. Commercial general liability insurance with coverage for premises/operations, personal injury, and contractual liability with combined single limits of liability of not less than \$2,000,000 for bodily injury and property damage per occurrence. This limit can be made through a combination of a primary commercial general liability policy and an umbrella policy or other multi-property "blanket" coverage.

Section 3. Each policy of insurance placed by Subtenant under this Sublease shall provide that such policy may not be canceled without at least thirty (30) days prior written notice to Landlord and Landlord's Mortgagee. Each policy of insurance placed by Landlord under this Sublease shall provide that such policy may not be canceled without at least thirty (30) days prior written notice to Subtenant. Each party shall furnish such policy or a certificate by the insurer as to the existence thereof to the other party at least thirty (30) days prior to the Commencement Date and thereafter at least fifteen (15) days prior to the expiration thereof or of any modification or renewal of such policy. Each of said policies shall be written on an annual basis with premiums to be prepaid yearly, and evidence of such payment shall be given to the other party not less than fifteen (15) days prior to the expiration of such policy.

Section 4. Each of Landlord and Subtenant hereby reSubleases the other (and each person and legal entity claiming through each of them) from any and all liability or responsibility to the other (and each person and legal entity claiming through the other) by way of subrogation or otherwise for any loss or damage to property caused by fire or any of the extended coverage casualties, or by sprinkler leakage, even if such fire or other casualty or such leakage shall have been caused by the fault or negligence of the other party, or anyone for whom such party may be responsible. This mutual waiver precludes the assignment of any such claim by subrogation to an insurance company (or any other person), and Landlord and Subtenant each agree to give written notice of this waiver to each insurance company that has issued or shall issue any property insurance policy to it, and to have the policy properly endorsed with provisions that either designate the other party as one of the insureds or deny to the insurer acquisition by

subrogation of rights of recovery against the other party to the extent such rights have been waived by the insured party, as set forth herein, insofar as, and to the extent that such provisions may be effective without making it impossible to obtain insurance coverage from responsible companies qualified to do business in the Commonwealth of Massachusetts (even though extra premium may result therefrom). Each party shall be entitled to have certificates of insurance with respect to such policies containing such provisions. In addition, and without limiting the foregoing, each of Landlord and Subtenant waives any and every such claim against the other that would have been covered had the insurance policies required to be maintained by such person by this Sublease been in force, to the extent that such loss or damage would have been recoverable under such policies, whether or not the same have been maintained.

### ARTICLE XV

### DAMAGE OR DESTRUCTION BY FIRE OR CASUALTY

Section 1. If so much of the Building shall be damaged or destroyed so that the remainder of the Building becomes uneconomic for Landlord's use in the good faith judgment of Landlord or if the time to repair the Building would exceed one hundred eighty (180) days, Landlord may terminate this Sublease by giving notice to Subtenant within thirty (30) days of such event.

Section 2. If this Sublease shall not be so terminated, Landlord, within a reasonable time, having in mind delays resulting from the settlement of any insurance loss, preparation of plans and obtaining permits, shall commence to restore the Subleased Premises. Landlord shall proceed reasonably diligently with such restoration. Landlord shall not be obligated to expend more than Landlord shall receive as insurance proceeds or otherwise on account of such damage or destruction, before taking into account deductions for deductibles or co-insurance. If Landlord fails to proceed with reasonable diligence or fails to complete restoration within ninety (90) days of its estimated completion date, Subtenant may, as its sole and exclusive remedy, terminate this Sublease by written notice to Landlord.

Section 3. If the Subleased Premises shall be damaged and if this Sublease shall not be terminated as herein provided, then the Annual Base Rent and Subtenant's Proportionate Share for all purposes shall be reduced for the portion of the Subleased Premises that cannot be used as a result of such damage until the Subleased Premises shall have been restored to its former condition.

#### ARTICLE XVI

#### EMINENT DOMAIN

Section 1. If after the Commencement Date the whole or substantially all of the Subleased Premises shall be taken under the power of eminent domain or by purchase in lieu thereof by any public, quasi-public or private authority, or condemned as unlawful, or suffer any

damage that shall entitle Landlord to make a claim for injury to the Building arising to the level of a taking, direct or consequential, all herein referred to as "Taking," then this Sublease shall, at the election of Landlord by written notice to Subtenant, be terminated.

Section 2. If after the Commencement Date:

- the aggregate of all reductions of the floor area of the Subleased Premises shall equal or exceed twenty (20%) or more of the original floor area of the Subleased Premises; or
- (ii) the Building shall be permanently deprived of access by motor vehicle to and from a public street or private way,

then, in either such case, Subtenant shall have the right at its election to terminate this Sublease by giving Landlord notice of its election within thirty (30) days after such event; provided, however, in the case of (ii) that if Landlord shall have undertaken to provide substitute access and Landlord shall have completed the same within thirty (30) days, Subtenant's notice of termination shall be void.

Section 3. All damages awarded for any Taking, whether for the whole or a part of the Subleased Premises, or the Building or otherwise, shall belong to and be the sole property of the Landlord whether such damages shall be awarded as compensation for diminishing the value of the Subleasehold, fee or otherwise, and Subtenant does hereby assign to Landlord all of its right, title, and interest thereto; provided, however, that Subtenant shall be entitled to receive and retain any amounts which may be specifically awarded to it by reason of the loss of its furniture or trade fixtures or for moving expenses. Subtenant agrees to execute and deliver any document necessary or desirable to confirm Landlord's rights under this Article XVI, Section 3.

Section 4. If this Sublease shall not be terminated as provided in Article XVI, Section 1, Landlord shall, within a reasonable period of time after such damage, commence to restore the damage or destruction to the Subleased Premises. Landlord shall proceed with reasonable diligence to the completion of such restoration so that they shall have been restored as nearly as possible to the condition they were in prior to such damage. If Landlord fails to proceed with reasonable diligence or fails to complete restoration within ninety (90) days of its estimated completion date, Subtenant may, as its sole and exclusive remedy, terminate this Sublease by written notice to Landlord. If the net award after all costs and expenses incurred by Landlord in the collection thereof shall not be sufficient to restore the Building, Landlord may terminate this Sublease by written notice to that effect to the Subtenant.

Section 5. During the period of restoration, the Annual Base Rent reserved hereunder shall be suspended or abated according to the proportion of the floor area of the Subleased Premises rendered unusable and Subtenant's Proportionate Share for all purposes shall be adjusted in accordance with Article III, Section 3. There shall be no abatement or suspension of Rent hereunder if there shall be no actual physical damage to the Subleased Premises, nor, in any case shall there be an abatement of Subtenant's obligation to pay other charges due under this

Sublease. If Subtenant shall be permanently deprived of any portion of the floor area of the Subleased Premises, the Annual Base Rent shall be proportionally abated for the balance of the Term (including the Extension Period, if applicable) to reflect the then size of the Subleased Premises and the Building and Subtenant's Proportionate Share for all purposes shall be adjusted in accordance with Article III, Section 3.

### ARTICLE XVII

### SUBTENANT DEFAULT

Section 1. Subtenant shall be deemed in default hereunder if, after receipt from Landlord of the required notice and the expiration of the applicable cure period (each as described more fully below), (a) Subtenant shall neglect or fail to make any payment of Annual Base Rent, Additional Rent or other payments to be made by it hereunder or shall neglect or fail to perform or observe any of the other material covenants and agreements contained in this Sublease and on its part to be performed or observed, (b) the estate created hereby shall be taken upon execution, attachment, or any other process of law and such process shall not be rendered inoperative within twenty (20) days thereafter, (c) Subtenant shall be adjudged a bankrupt or insolvent, or if any receiver or trustee of all or any part of the business or property of Subtenant, wherever located, shall be appointed and shall not be discharged within ninety (90) days after appointment, (d) Subtenant shall make any general assignment of its property for the benefit of creditors, or if Subtenant shall file a voluntary petition in bankruptcy or insolvency or shall apply for reorganization or arrangement with its creditors under the bankruptcy or insolvency laws now in force or hereinafter enacted, federal, state or otherwise, or if any such petition shall be filed against Subtenant and shall not be discharged within ninety (90) days after the filing, provided that the rent and all other monetary obligations of Subtenant shall be paid, or (e) Subtenant shall seek a composition with its creditors by trust mortgage or otherwise. Anything herein contained to the contrary notwithstanding, Subtenant shall not be in default until it receives written notice from Landlord of one or more of (a) through (e) above, as applicable, and is given the opportunity to cure the same, as follows. If such potential default shall relate to the payment of money, Subtenant shall have five (5) days to make payment. If such potential default shall be other than the payment of money, Subtenant shall have thirty (30) days to cure, provided that if the potential default complained of is of such character that it reasonably requires more than thirty (30) days to cure the same, Subtenant shall have a reasonable period of time, not to exceed sixty (60) days, subsequent to such thirty (30) day period, provided that Subtenant shall commence to cure such potential default within such thirty (30) day period and proceed diligently until completion of such cure. Landlord shall not exercise any remedy hereunder if Subtenant shall complete the cure of any potential default within the time periods allowed above.

Section 2. If Subtenant shall be in default under this Sublease as specified in Article XVII, Section 1 above, then in any such case Landlord may terminate this Sublease upon notice to Subtenant, and this Sublease shall come to an end on the date of such notice (or such other date specified for termination therein) as fully and completely as if such date were the date herein originally fixed for the expiration of the Term, and Subtenant will then quit and surrender the Subleased Premises to Landlord, but Subtenant shall remain liable as hereinafter provided. If

Subtenant is in default hereunder, Landlord also shall have the right when it delivers notice of termination or at any time thereafter, to enter upon the Subleased Premises or any part thereof in the name of the whole and repossess the same as of its former estate and expel Subtenant and those claiming by, through or under it, and remove their goods and effects without being deemed guilty of any manner of trespass and without prejudice to any remedies which might otherwise be used for arrears of rent or other payments or preceding breach of covenant.

Section 3. In the event of termination under Article XVII, Section 2, Subtenant shall pay to Landlord, as liquidated current damages, the Annual Base Rent, Additional Rent and other sums that would be payable hereunder for the remainder of the Term, or the Extension Period if the option under Article II, Section 2 was already exercised, if such termination had not occurred, less the net proceeds, if any, of any reletting of the Subleased Premises, after deducting all reasonable expenses in connection with such reletting, including, without limitation, all repossession costs, brokerage commissions, legal expenses, attorneys' fees, and advertising for such reletting. Subtenant shall pay the liquidated current damages to Landlord monthly on the days when the Annual Base Rent would have been payable hereunder if this Sublease had not been terminated. Landlord shall apply the Security Payments provided for in Article XVII, Section 2 to the liquidated current damages.

Section 4. If Subtenant shall be in default hereunder, Landlord may, at its option, without waiving any claim for breach of agreement, at any time thereafter cure such default for the account of Subtenant, and Subtenant shall reimburse Landlord for any amount paid and any expense or contractual liability so incurred, including reasonable attorneys' fees. Landlord may cure the default of Subtenant prior to the expiration of the cure period, but only after notice, which notice need not be in writing if confirmed forthwith by notice in writing to the Subtenant if it is necessary to protect the real estate or the interest of Landlord therein or to prevent injury or damage to persons or property. Any amount payable by Subtenant to Landlord pursuant to the provisions of this Article XVII, Section 4 shall be paid as part of and at the time for payment of the next installment of Annual Base Rent thereafter coming due.

### ARTICLE XVIII

### LANDLORD'S DEFAULT

Section 1. Landlord's failure to perform or observe any of its Sublease obligations after a period of thirty (30) business days or the additional time, if any, that is reasonably necessary to promptly and diligently cure the failure after receiving notice from Subtenant, or such lesser time as expressly provided elsewhere in this Sublease, is a default. The notice shall give in reasonable detail the nature and extent of the failure and identify the Sublease provision(s) containing the obligation(s). If Landlord commits a default, Subtenant may pursue any remedies given in this Sublease or under the law, provided, however, that in no event (unless otherwise specified herein) shall Subtenant have a right to offset Annual Base Rent or Additional Rent as a result of an alleged default hereunder.

#### ARTICLE XIX

### ASSIGNMENT AND SUBLETTING

Section 1. Except as herein expressly set forth, Subtenant shall not assign this Sublease nor any estate of interest therein, nor sublet or license the whole or any part of the Subleased Premises, all of which are herein referred to as a "Transfer," without the prior written consent of Landlord, not to be unreasonably withheld or delayed. Subtenant may Transfer its interest to any parent corporation or wholly-owned subsidiary corporation or wholly-owned subsidiary of any parent corporation without such consent, provided that in each case Subtenant shall give notice of such Transfer to Landlord. Each such assignee shall assume the obligations of the Subtenant hereunder. Subtenant shall remain liable to Landlord during the Term (including the Extension Period, if applicable) for the payment of rent and the performance of all obligations of Subtenant hereunder. Consent by Landlord to one or more Transfers shall not operate to exhaust Landlord's right to refuse consent to any future Transfer. Subtenant shall notify Landlord promptly of any proposed Transfer.

#### ARTICLE XX

### OVERSUBLEASES, MORTGAGES

Section 1. At the election of Landlord, or any future mortgagee, or any person who is or shall become the owner of the fee of the Building and who has or shall Sublease the same to Landlord, herein "Overlessor," which election may be changed from time to time, this Sublease and the Subtenant's rights hereunder shall be subject and subordinate to such mortgage or OverSublease; provided that such mortgagee or Overlessor shall first enter into a written instrument in recordable form and otherwise in form reasonably satisfactory to Subtenant, which provides that so long as no default, after the giving of any required notice and expiration of all grace or cure periods, is continuing hereunder: (i) this Sublease will not be affected and will continue as a direct Sublease between Subtenant and any such mortgagee or Overlessor and their assignees, nominees or successors (including, but not limited to, purchasers at a foreclosure sale) taking title to the Building or the Property or otherwise succeeding to the interest of Landlord hereunder, (ii) such mortgagee or Overlessor shall be prospectively bound to Subtenant under the terms of this Sublease (including Subtenant's right to extend the Term hereof), (iii) Subtenant's possession hereunder will not be disturbed by any default in, termination, foreclosure of, exercise of any remedy under such mortgage or OverSublease and/or any conveyance in lieu of the exercise thereof, as the case may be and (iv) Subtenant shall attorn to such mortgagee or Overlessor hereunder upon such mortgagee or Overlessor or their assignees, nominees or successors (including, but not limited to, purchasers at a foreclosure sale) taking title to the Building or the Property or otherwise succeeding to the interest of Landlord hereunder. Subtenant shall, upon request of Landlord, such mortgagee, or Overlessor, execute any documents which may be necessary to evidence or confirm such subordination.

Section 2. Subtenant shall, upon receipt of written notice from any such mortgagee, Overlessor, or other person to whom Landlord may from time to time assign the rents or other payments due hereunder, make payment of such rents or other payment to such person and shall be fully protected in making such payment. Landlord shall advise Subtenant in writing if Landlord shall hereafter grant a mortgage or OverSublease or otherwise assign the rents hereunder.

### ARTICLE XXI

### BROKER

Section 1. Landlord and Subtenant warrant and represent to each other that neither has dealt with any broker or agent in connection with this Sublease except Meredith & Grew Incorporated and Richards Barry Joyce & Partners, and that no other broker or agent has been instrumental in this transaction. Both parties agree to indemnify the other against any claim, loss, damage, cost or liability for any brokerage commission or fee which may be asserted against either party in connection with this Sublease by any other broker with whom either party has dealt.

### ARTICLE XXII

### NOTICES

Section 1. Except as specifically otherwise provided in this Sublease, all notices and other communications authorized or required hereunder shall be in writing and shall be given by mailing the same by certified or registered mail, return receipt requested, postage prepaid, or by expedited overnight courier utilizing receipt, or by facsimile confirmed in one of the foregoing methods, and any such notice shall be deemed to have been given when so mailed. If intended for Landlord, the same shall be mailed to Landlord at:

> Dr. Frank Pompei C/o Exergen Corporation 51 Water Street Watertown. MA 02472

with a copy contemporaneously sent to:

Walter H. McLaughlin, Jr., Esq. Gilman, McLaughlin & Hanrahan LLP 101 Merrimac Street P.O. Box 9601 Boston, Massachusetts 02114-9601

with copies to such other parties as Landlord shall designate, and if intended for Subtenant, the same shall be mailed to Subtenant at:

Control Delivery Systems, Inc. 400 Pleasant Street Watertown, Massachusetts 02472 Attention: Cristin L. Rothfuss, Corporate Counsel

with a copy contemporaneously sent to:

Mary Weber, Esq. Ropes & Gray, LLP One International Place Boston, MA 02110-2624

All notices shall be effective upon receipt or the third business day after deposit with the United States Post Office, postage paid.

### ARTICLE XXIII

### SECURITY DEPOSIT

Section 1. As security for its full and faithful performance of this Sublease during the original Term, Subtenant shall make the following payments (each a "Security Payment"): for each of the first six (6) months of the Term, Subtenant shall make an \$18,000 Security Payment to Landlord and commencing on the seventh month of the Term and continuing until the total Annual Base Rent for the original Term is paid in full, Subtenant shall make a \$20,000 Security Payment to Landlord each month. Each Security Payment shall be paid in conjunction with and be in addition to Subtenant's monthly installment of Annual Base Rent and Additional Rent. The first such Security Payment shall be applied against the monthly installment of Annual Base Rent due for the eighteenth (18th) month of the Term. The second such Security Payment shall be applied against the balance for the monthly installment of Annual Base Rent due for the eighteenth (18th) month of the Term, and the remainder shall be applied against the monthly installment of Annual Base Rent due for the seventeenth (17th) month of the Term. Other Security Payments shall be applied in the same manner (i.e., against the latest unpaid Annual Base Rent installment). Subtenant shall continue to make such payments and such payments shall continue to be applied in this manner until the total Annual Base Rent for the original Term is paid in full.

Section 2. In the event that this Sublease is terminated prior to the end of the original Term, and so long as Subtenant is not in default under any of the terms, provisions or conditions of this Sublease on the termination date, Landlord shall refund to Subtenant any amounts paid by Subtenant in excess of the Annual Base Rent due for the actual term length by virtue of the Security Payment mechanism described in Article XXIII, Section 1.

### ARTICLE XXIV

### MISCELLANEOUS

Section 1. In any case where either party hereto is required to do any act, other than the making of any payment of rent or other monetary sum due Landlord hereunder, the time for performance thereof shall be extended for a period equal to any delay caused by or resulting from any act of God, war, civil commotion, fire casualty, labor difficulties, shortages of labor, materials or equipment, governmental regulations or other causes beyond such party's reasonable control, whether such time be designated by a fixed date, a fixed time, or a "reasonable time." In no event shall the parties inability to pay a monetary sum be affected by this clause.

Section 2. Failure of either party to complain of any act or omission on the part of the other party, no matter how long the same may continue, shall not be deemed to be a waiver by said party of any of its rights hereunder. No waiver by either party at any time shall be effective unless in writing and signed by the party adversely affected by the breach with respect to which waiver is asserted to have been made. No waiver of any breach of any provision of this Sublease shall be deemed a waiver of a breach of any other provision of this Sublease or a consent to any subsequent breach of the same or any other provision. If any action by either party shall require the consent or approval of the other party, the other party's consent to or approval of such action on any one occasion shall not be deemed a consent to or approval of said action on any subsequent occasion or a consent or approval of any other action on the same or any subsequent occasion. Each and every right and remedy which either party may have under this Sublease or by operation of law, either at law or in equity, with respect to any breach, shall be distinct and separate from every other such right and remedy; all such rights and remedies shall be cumulative, and none of them shall be deemed inconsistent with any other, no such right or remedy whether or not exercised, shall be deemed to be in exclusion of any other, and any two or more or all of such rights and remedies may be exercised at the same time or successively, except where in this Sublease otherwise expressly provided.

Section 3. If any term or provision of this Sublease or the application thereof to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Sublease, or the application of such term or provisions to Persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term and provision of this Sublease shall be valid and be enforced to the fullest extent permitted by law.

Section 4. Except as herein otherwise provided, the terms and provisions of this Sublease shall be binding upon and inure to the benefit of the heirs, legal representatives, successors, and assigns respectively of Landlord and Subtenant. This Article XXIV, Section 4 shall not be deemed to be any consent by Landlord to an assignment hereof by Subtenant.

Section 5. The headings used for the various Articles of this Sublease are used only as a matter of convenience for reference, and are not to be construed as part of this Sublease or to be

used in determining the intent of the parties to this Sublease.

Section 6. This instrument constitutes the entire and only agreement between the parties and no oral statements or representations or prior written matters not contained in this Sublease shall have any force and effect. Except as expressly provided in this Sublease, none of the exhibits herein referred to or attached hereto shall in any way constitute any representation or warranty in respect to the Building, the Subleased Premises, location of construction and location of Buildings and improvements, occupancy by other Subtenants, continuation of occupancy by other Subtenants, use by other Subtenants, nor limitation on the construction of additional Buildings or additions to Building by Landlord whether on the roof, if any, of the Subleased Premises, or elsewhere. No subsequent amendments, changes, or additions to this Sublease shall be binding upon Landlord or Subtenant unless reduced to writing and duly executed by Landlord and Subtenant. Any pronoun shall be read in the singular or plural in such gender as the context may require or permit.

Section 7. Subtenant shall from time to time, upon request of Landlord, furnish to Landlord or to any designee of Landlord, certifications as to the status of this Sublease, the existence or non-existence of default on the part of Landlord, or any state of fact or facts requested to be certified to by Subtenant with reference to this Sublease.

Section 8. Except as otherwise expressly set forth herein, this Sublease is a net Sublease, and shall be interpreted to the end that the Annual Base Rent and Additional Rent shall be payable to Landlord without offset or deduction in any and all events, except as herein expressly set forth. Landlord shall have no obligation hereunder except as expressly set forth in this Sublease.

Section 9. So long as Subtenant shall not be in default, Subtenant may peaceably and quietly occupy and enjoy the Subleased Premises and the use thereof, without molestation of any person or any claims by, through or under Landlord.

Section 10. This Sublease may be executed in counterparts, each of which shall be deemed an original and all of which, taken together, shall be deemed to be one and the same instrument.

Section 11. The liability of Landlord hereunder shall be limited solely to the equity of Landlord in the Building and any sales or insurance proceeds realized therefrom, and in no case shall Landlord or any partner or agent of Landlord ever be personally liable beyond the extent of his or their equity in the Building or such proceeds for the obligations of Landlord, except that any of the same may be named in order to obtain jurisdiction of Landlord in any litigation. Each Landlord hereunder shall be liable for the obligations of Landlord only during such time as such person shall be Landlord and with respect only to items occurring during such period of ownership.

Section 12. The terms of this Sublease shall be not be disclosed by either party to any  $% \left( {{{\left[ {{{L_{\rm{s}}}} \right]}_{\rm{s}}}} \right)$ 

third party; provided, however, that each party may disclose such terms to its financial advisors and potential investors or in connection with a potential merger or acquisition, in each case under the auspices of a confidentiality agreement.

### ARTICLE XXV

### WORK LETTER

Section 1. Subtenant enters into this Sublease subject to Landlord's agreement to complete certain demising work and improvements no later than sixty (60) days after the Closing Date. In particular, Landlord agrees to complete all work specified in Exhibit C. Landlord shall be responsible for all costs associated with upgrading the bathrooms, as specified in Exhibit B. In addition, Landlord shall be responsible for the first \$25,000 of completing all other work specified in Exhibit B and any Additional Work, as defined below. Landlord and Subtenant shall each be responsible for fifty percent (50%) of the balance for completing all other work specified in Exhibit B and any Additional Work.

Section 2. Until the work associated with upgrading the bathrooms is completed, Subtenant's employees and guests shall be entitled to use the bathrooms in Landlord's portion of the Building. Landlord shall use all reasonable efforts to minimize disruption to Subtenant's business during performance of the work.

Section 3. If, no later than six (6) months after the Commencement Date, a local, state or federal governmental body having appropriate authority orders Landlord to perform demising work beyond that specified in Exhibit B ("Additional Work"), Landlord shall complete the same. Landlord and Subtenant shall be responsible for the cost of the Additional Work as set forth above. In the event that Subtenant is responsible for any part of the cost of the Additional Work, Landlord agrees to pay Subtenant's fifty percent (50%) share and Subtenant agrees to increase each monthly payment of Annual Base Rent during the remainder of the Term by an amount equal to such fifty percent (50%) share divided by the remaining number of Annual Base Rent payments.

 $\ensuremath{\mathsf{EXECUTED}}$  as a Sealed Instrument on the day, month and year first above written.

SUBTENANT:

CONTROL DELIVERY SYSTEMS, INC.

LANDLORD:

EXERGEN CORPORATION

By: /s/ Michael J. Soja ------Name: Michael J. Soja Office: VP and CFO Hereunto duly authorized

By: /s/ Francesco Pompei Francesco Pompei, President Hereunto duly authorized

Overlandlord hereby consents to this Sublease.

FHP, LLC

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By: /s/ Francesco Pompei
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Francesco Pompei, Manager
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EXHIBIT A

FLOOR PLAN

# EXHIBIT B

## REFERENCE YEAR

## AMOUNTS INCURRED BY LANDLORD AT HIS FORMER PROPERTY

	Water/sewer	Maint. Contracts	Electric	Gas	TOTAL
Dec-03	\$		\$ 3,275	\$ 962	\$ 4,237
Jan-04			3,622	1,345	4,968
Feb-04			2,655	1,102	3,756
Mar-04			3,513	1,054	4,566
Apr-04			3,513	418	3,931
May-04			3,776	94	3,870
Jun-04			6,796	93	6,889
Jul-04			5,737	99	5,836
Aug-04			6,924	94	7,018
Sep-04			6,394	90	6,484
Oct-04			6,394	366	6,761
Nov-04			4,342	366	4,708
Total	\$ \$	\$	\$ 56,941	\$ 6,084	\$ 63,025

AMOUNTS INCURRED BY SUBTENANT AT ITS FORMER PROPERTY

	Water/sew	er Maint. Contract	s Electric	Gas	TOTAL
Dec-03	\$ 175	\$ 1,333	\$ 11,139	\$ 6,931	\$ 19,578
Jan-04	175	1,333	11,239	6 <b>,</b> 562	19,309
Feb-04	175	1,334	10,233	7,367	19,110
Mar-04	175	1,333	9,922	7,402	18,832
Apr-04	175	1,333	10,322	5,820	17,650
May-04	175	1,334	11,182	5,604	18,295
Jun-04	175	1,333	15,149	4,683	21,340
Jul-04	175	1,333	17,082	4,730	23,321
Aug-04	175	1,334	17,053	4,220	22,782
Sep-04	175	1,333	13,376	4,747	19,631
Oct-04	175	1,333	17,623	4,545	23,676
Nov-04	175	1,334	9,264	5,107	15,880
Total	\$ 2,100	\$ 16,000	\$153,585	\$ 67,717	\$239,402

## EXHIBIT C

# WORK PLAN

1.	Bottom of Ramp in entrance front of building, straighten approx. 20' of wall 10'h removing existing double swing door and reinstall in another location. Wall single thickness 5/8" sheet rock T.J.P.	Ş	4,000
2.	Back section of building straighten wall approx. 17'L x 10'H. Removing existing doors and not reinstall with single 5/8 sheet rock T.J.P.	Ş	2,800
3.	Building divider wall 34-6" x 10'h with two framed doors and hardware, to form a corridor to bath rooms. Includes drop ceiling, lighting, VT flooring. T.J.P with base cover. (Does not include sprinkler system)	Ş	8,200
4. 5.	In same area cut open in existing wall to gain access to area, and baths. Includes, framing 36"x84" opening for frame and door with all hardware.	Ş	1,400
7.	Build diagonal wall at bottom of ramp with frame 36" crash bar door to match existing doors wall approx. 9'Lx10'H single 5/8 sheet rock both sides T.J.P.	\$	3,200
	Install drop ceiling in space 34.5'x16' + 12"x16" adjacent to divider wall to baths includes; installing track for drop ceiling 2"x4" all ceiling tile and six 2'x4' light panels and switching. Excluding flooring.	\$	4,200
8.	Frame and install sheet rock T.J.P. 6'x8' opening to divide office space in front of building	\$	1,000
9.	Ramp outside extend to 18'L. Build with pressure treated lumber and pipe rail.	\$	2,800
	SUBTOTAL	\$	27,600
	Contractor mark-up20%	\$	5,520
	TOTAL	\$	33,120

### AMENDED AND RESTATED CONTROL DELIVERY SYSTEMS, INC. CHANGE OF CONTROL AGREEMENT

AGREEMENT made this 17th day of August, 2004, by and between Paul Ashton ("Executive") and Control Delivery Systems, Inc. (the "Company").

Whereas, the Board of Directors of the Company (the "Board") recognizes that, as is the case with many corporations, the possibility of a Change of Control (as defined in Exhibit A) may exist and that such possibility, and the uncertainty and questions which it may raise among management personnel, may result in the departure or distraction of management personnel to the detriment of the Company and its stockholders;

Whereas, the Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of members of the Company's management, including Executive, to their duties, to assisting the Board in assessing proposals with respect to a Change of Control and to advising the Board as to the best interests of the Company and its shareholders with respect to such potential Change of Control, without distraction and conflict arising from the possibility of a Change of Control; and

Whereas, the Board wishes to induce Executive and other members of management to remain in the employ of the Company and to assure them of fair severance should the employment of any of them terminate in specified circumstances following a Change of Control of the Company;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

1. Severance Benefits Following a Change of Control

(a) Entitlement to Severance Benefits. If during that period starting on the date of a Change of Control and ending on the second anniversary of the Change of Control, the Company terminates Executive's employment without Cause, or if Executive terminates his employment for Good Reason, the Company will, subject to Section 2 below, provide severance benefits to Executive as set forth below in this Section 1.

"Good Reason" means (i) failure by the Company to maintain Executive in the position of Chief Executive Officer and President including holding the title of and serving as Chief Executive Officer and President of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to provide Executive with Base Salary as well as with the compensation (including without limitation bonus and other incentive compensation) Executive was receiving immediately prior to the Change of Control and with Benefits, or (iv) relocation of Executive's principal place of work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.

"Cause" means only (a) willful malfeasance or gross negligence in the performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.

"Base Salary" means \$250,000, provided that in the event the Board in its sole discretion increases Executive's Base Salary above \$250,000, the Base Salary as so increased will be referred to as "Base Salary."

"Benefits" means the following plans, policies and arrangements (or in any successor or supplemental plans, policies or arrangements), if and to the extent maintained by the Company, in each case at a level appropriate to Executive's position as determined by the Board and in each case in accordance with the terms of the pertinent plan, policy or arrangement:

- (i) the Company's 2001 Incentive Plan;
- (ii) the Company's group medical plan;

(iii) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company;

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(iv) all the Company's equity plans in which executives of the Company participate;

(v) the Company's normal expense reimbursement policies; and

(vi) ordinary vacation arrangements provided to executive-level employees of the Company, including at least four weeks paid vacation in addition to Company holidays per year.

(b) Severance Benefits Following a Change of Control. The Company will provide severance benefits to Executive as follows:

(i) The Company will pay to Executive within 30 days of the termination a lump-sum cash amount equal to 200% of the sum of (x) Base Salary, plus (y) the greater of (1) 100 percent of his bonus for the completed year immediately preceding the Change of Control, and (2) 100 percent of his bonus for the immediately preceding employment year.

(ii) The Company will also pay to Executive within 30 days of the termination a pro-rata portion of his maximum bonus for the year of termination.

(A) For purposes of this Section 1(b), the maximum bonus payable in such year will be calculated assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the termination of Executive's employment, agreed on such targets or formulas.

(B) If no such targets or formulas have been set as of such termination date, then the maximum bonus shall be deemed to be the greater of (x) 100 percent of his bonus for the completed year immediately preceding the Change of Control, and (y) 100 percent of his bonus for the immediately preceding employment year.

(iii) The Company will continue for a period of two years from the date of termination to provide Executive with medical benefits under the Company's group medical plan and life insurance arrangements and disability arrangements provided to executive level employees of the Company. To the extent the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will either arrange to provide Executive with substantially similar benefits upon comparable terms or pay Executive cash amounts equal to Executive's cost of obtaining such benefits.

(iv) All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable upon such termination and remain exercisable for a period of one year following such termination, and all restricted stock held by Executive under restricted stock plans and arrangements of the Company shall automatically and immediately vest and no longer be subject to forfeiture upon such

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termination. The Company agrees that it will not exercise any right that the Company has to purchase, repurchase or reacquire all or any part of such vested stock.

## 2. Taxes on Severance Benefits.

2.1 Withholding. All payments required to be made by the Company hereunder to Executive or his dependents, beneficiaries, or estate will be subject to the withholding of such amounts relating to tax and/or other payroll deductions as may be required by law.

2.2 Section 4999 Excise Taxes. In the event that it is determined that any payment or benefit provided by the Company to or for the benefit of Executive, either under this Agreement or otherwise, will be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code or any successor provision(s) ("Section 4999"), the Company will, prior to the date on which any amount of the excise tax must be paid or withheld, make an additional lump-sum payment (the "Gross-up Payment") to Executive in an amount sufficient, after giving effect to all federal, state and other taxes and charges (including interest and penalties, if any) with respect to the gross-up payment, to make Executive whole for all taxes (including withholding taxes) and any associated interest and penalties, imposed under or as a result of Section 4999.

2.3 Selection of Accounting Firm. Determinations under this Section 2 will be made by PricewaterhouseCoopers, LLP or if PricewaterhouseCoopers, LLP is unable or unwilling to serve or if the Company and Executive otherwise determine, by another firm mutually agreed to by the Company and Executive (the "Firm"). The determinations of the Firm will be binding upon the Company and Executive except as the determinations are established in resolution (including by settlement) of a controversy with the Internal Revenue Service to have been incorrect. All fees and expenses of the Firm will be paid by the Company.

2.4 IRS Claims. If the Internal Revenue Service asserts a claim that, if successful, would require the Company to make a Gross-up Payment or an additional Gross-up Payment, the Company and Executive will cooperate fully in resolving the controversy with the Internal Revenue Service. The Company will make or advance such Gross-up Payments as are necessary to prevent Executive from having to bear the cost of payments made to the Internal Revenue Service in the course of, or as a result of, the controversy. The Firm will determine the amount of such Gross-up Payments or advances and will determine after final resolution of the controversy whether any advances must be returned by Executive to the Company. The Company will bear all expenses of the controversy and will gross Executive up for any additional taxes that may be imposed upon Executive as a result of its payment of such expenses.

3. Withholding. All payments required to be made by the Company to Executive under this Agreement will be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as may be required by law.

4. Fees and Expenses. In the event of Executive's termination of employment during that period starting on the date of a Change of Control and ending on the second anniversary of

-4-

the Change of Control, the Company will pay any and all fees and expenses (including legal fees and other costs of arbitration or litigation) that may be incurred by Executive in enforcing his rights under this Agreement.

5. No Duty to Mitigate. Benefits payable under this Agreement as a result of termination of Executive's employment will be considered severance pay in consideration of his past service and his continued service from the Effective Date, and his entitlement thereto will neither be governed by any duty to mitigate his damages by seeking further employment nor offset by any compensation that he may receive from other employment.

6. Confidentiality. Executive agrees to maintain the confidentiality of the Company's (and its related entities and projects) books, records, financial information, technical information, business plans and/or strategies, and other confidential matters unless required to make disclosure in the performance of his duties for the Company or as a result of a legal proceeding or other legally mandated cause. Executive further agrees to abide by all of the terms of the Confidentiality and Inventions Agreement dated as of

The parties recognize and agree that should the Company be required to pursue a claim against Executive under this Section 6, the Company will likely be required to seek injunctive relief as well as damages at law. Accordingly, Section 8, Arbitration, will not apply to any action by the Company against Executive for violation of this Section 6.

7. Indemnification. To the extent permitted by law, the Company will defend, indemnify and hold Executive harmless from and against any and all losses, liabilities, damages, expenses (including attorneys' fees and costs), actions, causes of action or proceedings arising directly or indirectly from Executive's performance of this Agreement or services as an employee of the Company. Executive may retain his own counsel to defend himself in such actions, and the Company will pay for the reasonable costs and expense of such counsel. This indemnification is in addition to any right of indemnification to which Executive may be entitled under the Company's Articles of Incorporation and By-laws, any separate indemnification agreements between the Company and Executive, and any insurance policies that may be maintained by the Company.

8. Arbitration. Except as otherwise provided in Section 6, any dispute or controversy between the parties involving the construction or application of any terms, covenants or conditions of this Agreement, or any claim arising out of or relating to this Agreement, or any claim arising out of or relating to Executive's employment by the Company that is not resolved within ten days by the parties will be settled by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The Company and Executive agree that the arbitrator(s) will have no authority to award punitive or exemplary damages or so-called consequential or remote damages such as damages for emotional distress. Any decision of the arbitrator(s) will be final and binding upon the parties. Either party may request that the arbitrator(s) submit written findings of fact and

-5-

conclusions of law. The parties agree and understand that they hereby waive their rights to a jury trial of any dispute or controversy relating to the matters specified above in this Section 8.

9. Rights of Survivors If Executive dies after becoming entitled to benefits under Section 1 following termination of employment but before all such benefits have been provided, (a) all unpaid cash amounts will be paid to the beneficiary that has been designated by Executive in writing (the "beneficiary"), or if none, to Executive's estate, (b) all applicable insurance coverage will be provided to Executive's family as though Executive had continued to live, and (c) any stock options that become exercisable under Section 1 will be exercisable by the beneficiary, or if none, the estate.

10. Successors. This Agreement will inure to and be binding upon the Company's successors. The Company will require any successor to all or substantially all of the business and/or assets of the Company by sale, merger or consolidation (where the Company is not the surviving corporation), lease or otherwise, by agreement in form and substance satisfactory to Executive, to assume this Agreement expressly. This Agreement is not otherwise assignable by the Company or the Executive.

11. Amendment or Modification; Waiver. This Agreement may not be amended unless agreed to in writing by Executive and the Company. No waiver by either party of any breach of this Agreement will be deemed a waiver of a subsequent breach.

12. Severability. In the event that any provision of this Agreement is determined to be invalid or unenforceable, the remaining provisions shall remain in full force and effect to the fullest extent permitted by law.

13. Controlling Law. This Agreement will be controlled and interpreted pursuant to Massachusetts law, other than its choice of law principles.

14. Entire Agreement. This Agreement (including without limitation the Exhibits hereto) constitutes the entire agreement and supersedes conflicting terms in all prior agreements and undertakings, both written and oral, between Executive and the Company with respect to the subject matter hereof. Except as otherwise set forth herein, the terms and conditions of all other agreements with Executive, including without limitation all Restricted Stock Award Agreements and a Confidentiality and Inventions Agreement, shall continue in full force and effect.

15. Notices. Any notices required or permitted to be sent under this Agreement are to be delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to the Company:

Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472

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Paul Ashton 19 Brimmer Street Boston, MA 02108

Either party may change its address for receiving notices by giving notice to the other party.

16. Release. Notwithstanding anything to the contrary contained in this Agreement, in order for Executive to be eligible for the severance benefits to be provided in accordance with this Agreement, Executive must sign (and not revoke within seven days of signing) a release of claims in the form attached hereto and marked Exhibit B.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]

In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Paul Ashton Name: Paul Ashton CONTROL DELIVERY SYSTEMS, INC. By: /s/ Lori H. Freedman Name: Lori H. Freedman Title: Vice President, Corporate Affairs and General Counsel

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### Exhibit A

"Change of Control" means the occurrence of any of the following events:

(a) The acquisition by any Person or group of the ultimate beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of more than 50% of the then outstanding securities of the Company entitled to vote generally in the election of directors; excluding, however, the following: (i) any acquisition directly from the Company (other than any acquisition by virtue of the exercise of an exercise, conversion or exchange privilege unless the security being so exercised, converted or exchanged was itself acquired directly from the Company); (ii) any acquisition by the Company; (iii) any acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company or by any corporation controlled by the Company; (iv) any acquisition by the Executive, by an Executive Related Party (as defined in Exhibit A) or by a group of which the Executive is a member; or (v) any acquisition by any corporation pursuant to a transaction which complies with clauses (i), (ii) and (iii) of subsection (c) of this Exhibit A; or

(b) Individuals who, as of the date hereof, constitute the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election, by the Company's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or

 $(\ensuremath{\mathtt{v}})$  A reorganization, recapitalization, merger or consolidation (a "Corporate Transaction") of the Company, unless (i) securities representing more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the Company or such corporation after such Corporate Transaction) are beneficially owned subsequent to such Corporate Transaction by the Person or Persons who were the beneficial owners of the outstanding securities of the Company entitled to vote generally in the election of directors immediately prior to such Corporate Transaction, in substantially the same proportions as their ownership immediately prior to such Corporate Transaction; (ii) no Person (excluding any corporation resulting from such Corporate Transaction or any employee benefit plan (or related trust) of the Company or such corporation resulting from such Corporate Transaction) ultimately beneficially owns, directly or indirectly, more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the

Company or such corporation after such Corporate Transaction) except to the extent that such ownership existed prior to the Corporate Transaction; and (iii) at least a majority of the members of the board of directors of the corporation resulting from such Corporate Transaction were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Corporate Transaction; or

(c) The sale, transfer or other disposition of all or substantially all of the assets of the Company; or

(vi) Approval by the shareholders of the Company of a complete liquidation or dissolution of the Company.

For purposes of this definition, securities entitled to vote generally in the election of directors that are issuable upon exercise of an exercise, conversion or exchange privilege shall be deemed to be outstanding. In addition, for purposes of this definition the following terms have the meanings set forth below:

A Person will be deemed to be the "owner" of any securities of which such Person would be the "beneficial owner," as such term is defined in Rule 13d-3 promulgated by the Securities and Exchange Commission under the Exchange Act.

"Person" has the meaning used in Section 13(d) of the Exchange Act, except that "Person" does not include (i) the Executive, an Executive Related Party, or any group of which the Executive or Executive Related Party is a member, or (ii) the Company or a wholly owned subsidiary of the Company or an employee benefit plan (or related trust) of the Company or of a wholly owned subsidiary.

An "Executive Related Party" means any affiliate or associate of the Executive other than the Company or a subsidiary of the Company. The terms "affiliate" and "associate" have the meanings given in Rule 12b-2 under the Exchange Act; the term "registrant" in the definition of "associate" means, in this case, the Company.

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#### EXHIBIT B

### RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the Amended and Restated Change of Control Agreement between me and Control Delivery Systems, Inc. (the "Company") dated as of August 17, 2004 (the "Agreement"), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executives, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or any of its subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Articles of Incorporation or By-Laws of the Company or any of its subsidiaries or other affiliates.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its Affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the Company and that this

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Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature:					
Name	(please	print):			
Date	Signed:				

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### AMENDED AND RESTATED CONTROL DELIVERY SYSTEMS, INC. CHANGE OF CONTROL AGREEMENT

AGREEMENT made this 17th day of August, 2004, by and between Michael J. Soja ("Executive") and Control Delivery Systems, Inc. (the "Company").

Whereas, the Board of Directors of the Company (the "Board") recognizes that, as is the case with many corporations, the possibility of a Change of Control (as defined in Exhibit A) may exist and that such possibility, and the uncertainty and questions which it may raise among management personnel, may result in the departure or distraction of management personnel to the detriment of the Company and its stockholders;

Whereas, the Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of members of the Company's management, including Executive, to their duties, to assisting the Board in assessing proposals with respect to a Change of Control and to advising the Board as to the best interests of the Company and its shareholders with respect to such potential Change of Control, without distraction and conflict arising from the possibility of a Change of Control; and

Whereas, the Board wishes to induce Executive and other members of management to remain in the employ of the Company and to assure them of fair severance should the employment of any of them terminate in specified circumstances following a Change of Control of the Company;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

1. Severance Benefits Following a Change of Control

(a) Entitlement to Severance Benefits. If during that period starting on the date of a Change of Control and ending on the second anniversary of the Change of Control, the Company terminates Executive's employment without Cause, or if Executive terminates his employment for Good Reason, the Company will, subject to Section 2 below, provide severance benefits to Executive as set forth below in this Section 1.

"Good Reason" means (i) failure by the Company to maintain Executive in the position of Vice President, Chief Financial Officer including holding the title of and serving as Vice President, Chief Financial Officer of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to provide Executive with Base Salary as well as with the compensation (including without limitation bonus and other incentive compensation) Executive was receiving immediately prior to the Change of Control and with Benefits, or (iv) relocation of Executive's principal place of work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.

"Cause" means only (a) willful malfeasance or gross negligence in the performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.

"Base Salary" means \$272,497, provided that in the event the Board in its sole discretion increases Executive's Base Salary above \$272,497, the Base Salary as so increased will be referred to as "Base Salary."

"Benefits" means the following plans, policies and arrangements (or in any successor or supplemental plans, policies or arrangements), if and to the extent maintained by the Company, in each case at a level appropriate to Executive's position as determined by the Board and in each case in accordance with the terms of the pertinent plan, policy or arrangement:

- (i) the Company's 2001 Incentive Plan;
- (ii) the Company's group medical plan;

(iii) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company;

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(iv) all the Company's equity plans in which executives of the Company participate;

(v) the Company's normal expense reimbursement policies; and

(vi) ordinary vacation arrangements provided to executive-level employees of the Company, including at least four weeks paid vacation in addition to Company holidays per year.

(b) Severance Benefits Following a Change of Control. The Company will provide severance benefits to Executive as follows:

(i) The Company will pay to Executive within 30 days of the termination a lump-sum cash amount equal to 200% of the sum of (x) Base Salary, plus (y) the greater of (1) 100 percent of his bonus for the completed year immediately preceding the Change of Control, and (2) 100 percent of his bonus for the immediately preceding employment year.

(ii) The Company will also pay to Executive within 30 days of the termination a pro-rata portion of his maximum bonus for the year of termination.

(A) For purposes of this Section 1(b), the maximum bonus payable in such year will be calculated assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the termination of Executive's employment, agreed on such targets or formulas.

(B) If no such targets or formulas have been set as of such termination date, then the maximum bonus shall be deemed to be the greater of (x) 100 percent of his bonus for the completed year immediately preceding the Change of Control, and (y) 100 percent of his bonus for the immediately preceding employment year.

(iii) The Company will continue for a period of two years from the date of termination to provide Executive with medical benefits under the Company's group medical plan and life insurance arrangements and disability arrangements provided to executive level employees of the Company. To the extent the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will either arrange to provide Executive with substantially similar benefits upon comparable terms or pay Executive cash amounts equal to Executive's cost of obtaining such benefits.

(iv) All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable upon such termination and remain exercisable for a period of one year following such termination, and all restricted stock held by Executive under restricted stock plans and arrangements of the Company shall automatically and immediately vest and no longer be subject to forfeiture upon such

-3-

termination. The Company agrees that it will not exercise any right that the Company has to purchase, repurchase or reacquire all or any part of such vested stock.

## 2. Taxes on Severance Benefits.

2.1 Withholding. All payments required to be made by the Company hereunder to Executive or his dependents, beneficiaries, or estate will be subject to the withholding of such amounts relating to tax and/or other payroll deductions as may be required by law.

2.2 Section 4999 Excise Taxes. In the event that it is determined that any payment or benefit provided by the Company to or for the benefit of Executive, either under this Agreement or otherwise, will be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code or any successor provision(s) ("Section 4999"), the Company will, prior to the date on which any amount of the excise tax must be paid or withheld, make an additional lump-sum payment (the "Gross-up Payment") to Executive in an amount sufficient, after giving effect to all federal, state and other taxes and charges (including interest and penalties, if any) with respect to the gross-up payment, to make Executive whole for all taxes (including withholding taxes) and any associated interest and penalties, imposed under or as a result of Section 4999.

2.3 Selection of Accounting Firm. Determinations under this Section 2 will be made by PricewaterhouseCoopers, LLP or if PricewaterhouseCoopers, LLP is unable or unwilling to serve or if the Company and Executive otherwise determine, by another firm mutually agreed to by the Company and Executive (the "Firm"). The determinations of the Firm will be binding upon the Company and Executive except as the determinations are established in resolution (including by settlement) of a controversy with the Internal Revenue Service to have been incorrect. All fees and expenses of the Firm will be paid by the Company.

2.4 IRS Claims. If the Internal Revenue Service asserts a claim that, if successful, would require the Company to make a Gross-up Payment or an additional Gross-up Payment, the Company and Executive will cooperate fully in resolving the controversy with the Internal Revenue Service. The Company will make or advance such Gross-up Payments as are necessary to prevent Executive from having to bear the cost of payments made to the Internal Revenue Service in the course of, or as a result of, the controversy. The Firm will determine the amount of such Gross-up Payments or advances and will determine after final resolution of the controversy whether any advances must be returned by Executive to the Company. The Company will bear all expenses of the controversy and will gross Executive up for any additional taxes that may be imposed upon Executive as a result of its payment of such expenses.

3. Withholding. All payments required to be made by the Company to Executive under this Agreement will be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as may be required by law.

4. Fees and Expenses. In the event of Executive's termination of employment during that period starting on the date of a Change of Control and ending on the second anniversary of

-4-

the Change of Control, the Company will pay any and all fees and expenses (including legal fees and other costs of arbitration or litigation) that may be incurred by Executive in enforcing his rights under this Agreement.

5. No Duty to Mitigate. Benefits payable under this Agreement as a result of termination of Executive's employment will be considered severance pay in consideration of his past service and his continued service from the Effective Date, and his entitlement thereto will neither be governed by any duty to mitigate his damages by seeking further employment nor offset by any compensation that he may receive from other employment.

6. Confidentiality. Executive agrees to maintain the confidentiality of the Company's (and its related entities and projects) books, records, financial information, technical information, business plans and/or strategies, and other confidential matters unless required to make disclosure in the performance of his duties for the Company or as a result of a legal proceeding or other legally mandated cause. Executive further agrees to abide by all of the terms of the Confidentiality and Inventions Agreement dated as of

The parties recognize and agree that should the Company be required to pursue a claim against Executive under this Section 6, the Company will likely be required to seek injunctive relief as well as damages at law. Accordingly, Section 8, Arbitration, will not apply to any action by the Company against Executive for violation of this Section 6.

7. Indemnification. To the extent permitted by law, the Company will defend, indemnify and hold Executive harmless from and against any and all losses, liabilities, damages, expenses (including attorneys' fees and costs), actions, causes of action or proceedings arising directly or indirectly from Executive's performance of this Agreement or services as an employee of the Company. Executive may retain his own counsel to defend himself in such actions, and the Company will pay for the reasonable costs and expense of such counsel. This indemnification is in addition to any right of indemnification to which Executive may be entitled under the Company's Articles of Incorporation and By-laws, any separate indemnification agreements between the Company and Executive, and any insurance policies that may be maintained by the Company.

8. Arbitration. Except as otherwise provided in Section 6, any dispute or controversy between the parties involving the construction or application of any terms, covenants or conditions of this Agreement, or any claim arising out of or relating to this Agreement, or any claim arising out of or relating to Executive's employment by the Company that is not resolved within ten days by the parties will be settled by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The Company and Executive agree that the arbitrator(s) will have no authority to award punitive or exemplary damages or so-called consequential or remote damages such as damages for emotional distress. Any decision of the arbitrator(s) will be final and binding upon the parties. Either party may request that the arbitrator(s) submit written findings of fact and

-5-

conclusions of law. The parties agree and understand that they hereby waive their rights to a jury trial of any dispute or controversy relating to the matters specified above in this Section 8.

9. Rights of Survivors If Executive dies after becoming entitled to benefits under Section 1 following termination of employment but before all such benefits have been provided, (a) all unpaid cash amounts will be paid to the beneficiary that has been designated by Executive in writing (the "beneficiary"), or if none, to Executive's estate, (b) all applicable insurance coverage will be provided to Executive's family as though Executive had continued to live, and (c) any stock options that become exercisable under Section 1 will be exercisable by the beneficiary, or if none, the estate.

10. Successors. This Agreement will inure to and be binding upon the Company's successors. The Company will require any successor to all or substantially all of the business and/or assets of the Company by sale, merger or consolidation (where the Company is not the surviving corporation), lease or otherwise, by agreement in form and substance satisfactory to Executive, to assume this Agreement expressly. This Agreement is not otherwise assignable by the Company or the Executive.

11. Amendment or Modification; Waiver. This Agreement may not be amended unless agreed to in writing by Executive and the Company. No waiver by either party of any breach of this Agreement will be deemed a waiver of a subsequent breach.

12. Severability. In the event that any provision of this Agreement is determined to be invalid or unenforceable, the remaining provisions shall remain in full force and effect to the fullest extent permitted by law.

13. Controlling Law. This Agreement will be controlled and interpreted pursuant to Massachusetts law, other than its choice of law principles.

14. Entire Agreement. This Agreement (including without limitation the Exhibits hereto) constitutes the entire agreement and supersedes conflicting terms in all prior agreements and undertakings, both written and oral, between Executive and the Company with respect to the subject matter hereof. Except as otherwise set forth herein, the terms and conditions of all other agreements with Executive, including without limitation all Restricted Stock Award Agreements and a Confidentiality and Inventions Agreement, shall continue in full force and effect.

15. Notices. Any notices required or permitted to be sent under this Agreement are to be delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to the Company:

Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472

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Michael J. Soja 34 Musket Lane Sudbury, MA 01776

Either party may change its address for receiving notices by giving notice to the other party.

16. Release. Notwithstanding anything to the contrary contained in this Agreement, in order for Executive to be eligible for the severance benefits to be provided in accordance with this Agreement, Executive must sign (and not revoke within seven days of signing) a release of claims in the form attached hereto and marked Exhibit B.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]

In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

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By: /s/ Michael J. Soja

Name: Michael J. Soja

CONTROL DELIVERY SYSTEMS, INC.

By: /s/ Paul Ashton

Name: Paul Ashton

Title: Chief Executive Officer &

President
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"Change of Control" means the occurrence of any of the following events:

(a) The acquisition by any Person or group of the ultimate beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of more than 50% of the then outstanding securities of the Company entitled to vote generally in the election of directors; excluding, however, the following: (i) any acquisition directly from the Company (other than any acquisition by virtue of the exercise of an exercise, conversion or exchange privilege unless the security being so exercised, converted or exchanged was itself acquired directly from the Company); (ii) any acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company or by any corporation controlled by the Company; (iv) any acquisition by a group of which the Executive Related Party (as defined in Exhibit A) or by a group of which the Executive is a member; or (v) any acquisition by any corporation pursuant to a transaction which complies with clauses (i), (ii) and (iii) of subsection (c) of this Exhibit A; or

(b) Individuals who, as of the date hereof, constitute the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election, by the Company's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or

 $(\ensuremath{\mathtt{v}})$  A reorganization, recapitalization, merger or consolidation (a "Corporate Transaction") of the Company, unless (i) securities representing more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the Company or such corporation after such Corporate Transaction) are beneficially owned subsequent to such Corporate Transaction by the Person or Persons who were the beneficial owners of the outstanding securities of the Company entitled to vote generally in the election of directors immediately prior to such Corporate Transaction, in substantially the same proportions as their ownership immediately prior to such Corporate Transaction; (ii) no Person (excluding any corporation resulting from such Corporate Transaction or any employee benefit plan (or related trust) of the Company or such corporation resulting from such Corporate Transaction) ultimately beneficially owns, directly or indirectly, more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the

Company or such corporation after such Corporate Transaction) except to the extent that such ownership existed prior to the Corporate Transaction; and (iii) at least a majority of the members of the board of directors of the corporation resulting from such Corporate Transaction were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Corporate Transaction; or

(c) The sale, transfer or other disposition of all or substantially all of the assets of the Company; or

(vi) Approval by the shareholders of the Company of a complete liquidation or dissolution of the Company.

For purposes of this definition, securities entitled to vote generally in the election of directors that are issuable upon exercise of an exercise, conversion or exchange privilege shall be deemed to be outstanding. In addition, for purposes of this definition the following terms have the meanings set forth below:

A Person will be deemed to be the "owner" of any securities of which such Person would be the "beneficial owner," as such term is defined in Rule 13d-3 promulgated by the Securities and Exchange Commission under the Exchange Act.

"Person" has the meaning used in Section 13(d) of the Exchange Act, except that "Person" does not include (i) the Executive, an Executive Related Party, or any group of which the Executive or Executive Related Party is a member, or (ii) the Company or a wholly owned subsidiary of the Company or an employee benefit plan (or related trust) of the Company or of a wholly owned subsidiary.

An "Executive Related Party" means any affiliate or associate of the Executive other than the Company or a subsidiary of the Company. The terms "affiliate" and "associate" have the meanings given in Rule 12b-2 under the Exchange Act; the term "registrant" in the definition of "associate" means, in this case, the Company.

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#### EXHIBIT B

### RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the Amended and Restated Change of Control Agreement between me and Control Delivery Systems, Inc. (the "Company") dated as of August 17, 2004 (the "Agreement"), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executives, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or any of its subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Articles of Incorporation or By-Laws of the Company or any of its subsidiaries or other affiliates.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its Affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the Company and that this

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Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature: Name (please print): Date Signed:

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### AMENDED AND RESTATED CONTROL DELIVERY SYSTEMS, INC. CHANGE OF CONTROL AGREEMENT

AGREEMENT made this 17th day of August, 2004, by and between Lori Freedman ("Executive") and Control Delivery Systems, Inc. (the "Company").

Whereas, the Board of Directors of the Company (the "Board") recognizes that, as is the case with many corporations, the possibility of a Change of Control (as defined in Exhibit A) may exist and that such possibility, and the uncertainty and questions which it may raise among management personnel, may result in the departure or distraction of management personnel to the detriment of the Company and its stockholders;

Whereas, the Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of members of the Company's management, including Executive, to their duties, to assisting the Board in assessing proposals with respect to a Change of Control and to advising the Board as to the best interests of the Company and its shareholders with respect to such potential Change of Control, without distraction and conflict arising from the possibility of a Change of Control; and

Whereas, the Board wishes to induce Executive and other members of management to remain in the employ of the Company and to assure them of fair severance should the employment of any of them terminate in specified circumstances following a Change of Control of the Company;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

1. Severance Benefits Following a Change of Control

(a) Entitlement to Severance Benefits. If during that period starting on the date of a Change of Control and ending on the second anniversary of the Change of Control, the Company terminates Executive's employment without Cause, or if Executive terminates his employment for Good Reason, the Company will, subject to Section 2 below, provide severance benefits to Executive as set forth below in this Section 1.

"Good Reason" means (i) failure by the Company to maintain Executive in the positions of Vice President, Corporate Affairs, General Counsel and Secretary including holding the title of and serving as Vice President, Corporate Affairs, General Counsel and Secretary of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to provide Executive with Base Salary as well as with the compensation (including without limitation, bonus and other incentive compensation) Executive was receiving immediately prior to the Change of Control and with Benefits, or (iv) relocation of Executive's principal place of work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.

"Cause" means only (a) willful malfeasance or gross negligence in the performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.

"Base Salary" means \$272,497, provided that in the event the Board in its sole discretion increases Executive's Base Salary above \$272,497, the Base Salary as so increased will be referred to as "Base Salary."

"Benefits"means the following plans, policies and arrangements (or in any successor or supplemental plans, policies or arrangements), if and to the extent maintained by the Company, in each case at a level appropriate to Executive's position as determined by the Board and in each case in accordance with the terms of the pertinent plan, policy or arrangement:

- (i) the Company's 2001 Incentive Plan;
- (ii) the Company's group medical plan;

(iii) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company;

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(iv) all the Company's equity plans in which executives of the Company participate;

(v) the Company's normal expense reimbursement policies; and

(vi) ordinary vacation arrangements provided to executive-level employees of the Company, including at least four weeks paid vacation in addition to Company holidays per year.

(b) Severance Benefits Following a Change of Control. The Company will provide severance benefits to Executive as follows:

(i) The Company will pay to Executive within 30 days of the termination a lump-sum cash amount equal to 200% of the sum of (x) Base Salary, plus (y) the greater of (1) 100 percent of his bonus for the completed year immediately preceding the Change of Control, and (2) 100 percent of his bonus for the immediately preceding employment year.

(ii) The Company will also pay to Executive within 30 days of the termination a pro-rata portion of his maximum bonus for the year of termination.

(A) For purposes of this Section 1(b), the maximum bonus payable in such year will be calculated assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the termination of Executive's employment, agreed on such targets or formulas.

(B) If no such targets or formulas have been set as of such termination date, then the maximum bonus shall be deemed to be the greater of (x) 100 percent of his bonus for the completed year immediately preceding the Change of Control, and (y) 100 percent of his bonus for the immediately preceding employment year.

(iii) The Company will continue for a period of two years from the date of termination to provide Executive with medical benefits under the Company's group medical plan and life insurance arrangements and disability arrangements provided to executive level employees of the Company. To the extent the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will either arrange to provide Executive with substantially similar benefits upon comparable terms or pay Executive cash amounts equal to Executive's cost of obtaining such benefits.

(iv) All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable upon such termination and remain exercisable for a period of one year following such termination, and all restricted stock held by Executive under restricted stock plans and arrangements of the Company shall automatically and immediately vest and no longer be subject to forfeiture upon such

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termination. The Company agrees that it will not exercise any right that the Company has to purchase, repurchase or reacquire all or any part of such vested stock.

# 2. Taxes on Severance Benefits.

2.1 Withholding. All payments required to be made by the Company hereunder to Executive or his dependents, beneficiaries, or estate will be subject to the withholding of such amounts relating to tax and/or other payroll deductions as may be required by law.

2.2 Section 4999 Excise Taxes. In the event that it is determined that any payment or benefit provided by the Company to or for the benefit of Executive, either under this Agreement or otherwise, will be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code or any successor provision(s) ("Section 4999"), the Company will, prior to the date on which any amount of the excise tax must be paid or withheld, make an additional lump-sum payment (the "Gross-up Payment") to Executive in an amount sufficient, after giving effect to all federal, state and other taxes and charges (including interest and penalties, if any) with respect to the gross-up payment, to make Executive whole for all taxes (including withholding taxes) and any associated interest and penalties, imposed under or as a result of Section 4999.

2.3 Selection of Accounting Firm. Determinations under this Section 2 will be made by PricewaterhouseCoopers, LLP or if PricewaterhouseCoopers, LLP is unable or unwilling to serve or if the Company and Executive otherwise determine, by another firm mutually agreed to by the Company and Executive (the "Firm"). The determinations of the Firm will be binding upon the Company and Executive except as the determinations are established in resolution (including by settlement) of a controversy with the Internal Revenue Service to have been incorrect. All fees and expenses of the Firm will be paid by the Company.

2.4 IRS Claims. If the Internal Revenue Service asserts a claim that, if successful, would require the Company to make a Gross-up Payment or an additional Gross-up Payment, the Company and Executive will cooperate fully in resolving the controversy with the Internal Revenue Service. The Company will make or advance such Gross-up Payments as are necessary to prevent Executive from having to bear the cost of payments made to the Internal Revenue Service in the course of, or as a result of, the controversy. The Firm will determine the amount of such Gross-up Payments or advances and will determine after final resolution of the controversy whether any advances must be returned by Executive to the Company. The Company will bear all expenses of the controversy and will gross Executive up for any additional taxes that may be imposed upon Executive as a result of its payment of such expenses.

3. Withholding. All payments required to be made by the Company to Executive under this Agreement will be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as may be required by law.

4. Fees and Expenses. In the event of Executive's termination of employment during that period starting on the date of a Change of Control and ending on the second anniversary of

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the Change of Control, the Company will pay any and all fees and expenses (including legal fees and other costs of arbitration or litigation) that may be incurred by Executive in enforcing his rights under this Agreement.

5. No Duty to Mitigate. Benefits payable under this Agreement as a result of termination of Executive's employment will be considered severance pay in consideration of his past service and his continued service from the Effective Date, and his entitlement thereto will neither be governed by any duty to mitigate his damages by seeking further employment nor offset by any compensation that he may receive from other employment.

6. Confidentiality. Executive agrees to maintain the confidentiality of the Company's (and its related entities and projects) books, records, financial information, technical information, business plans and/or strategies, and other confidential matters unless required to make disclosure in the performance of his duties for the Company or as a result of a legal proceeding or other legally mandated cause. Executive further agrees to abide by all of the terms of the Confidentiality and Inventions Agreement dated as of

The parties recognize and agree that should the Company be required to pursue a claim against Executive under this Section 6, the Company will likely be required to seek injunctive relief as well as damages at law. Accordingly, Section 8, Arbitration, will not apply to any action by the Company against Executive for violation of this Section 6.

7. Indemnification. To the extent permitted by law, the Company will defend, indemnify and hold Executive harmless from and against any and all losses, liabilities, damages, expenses (including attorneys' fees and costs), actions, causes of action or proceedings arising directly or indirectly from Executive's performance of this Agreement or services as an employee of the Company. Executive may retain his own counsel to defend himself in such actions, and the Company will pay for the reasonable costs and expense of such counsel. This indemnification is in addition to any right of indemnification to which Executive may be entitled under the Company's Articles of Incorporation and By-laws, any separate indemnification agreements between the Company and Executive, and any insurance policies that may be maintained by the Company.

8. Arbitration. Except as otherwise provided in Section 6, any dispute or controversy between the parties involving the construction or application of any terms, covenants or conditions of this Agreement, or any claim arising out of or relating to this Agreement, or any claim arising out of or relating to Executive's employment by the Company that is not resolved within ten days by the parties will be settled by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The Company and Executive agree that the arbitrator(s) will have no authority to award punitive or exemplary damages or so-called consequential or remote damages such as damages for emotional distress. Any decision of the arbitrator(s) will be final and binding upon the parties. Either party may request that the arbitrator(s) submit written findings of fact and

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conclusions of law. The parties agree and understand that they hereby waive their rights to a jury trial of any dispute or controversy relating to the matters specified above in this Section 8.

9. Rights of Survivors If Executive dies after becoming entitled to benefits under Section 1 following termination of employment but before all such benefits have been provided, (a) all unpaid cash amounts will be paid to the beneficiary that has been designated by Executive in writing (the "beneficiary"), or if none, to Executive's estate, (b) all applicable insurance coverage will be provided to Executive's family as though Executive had continued to live, and (c) any stock options that become exercisable under Section 1 will be exercisable by the beneficiary, or if none, the estate.

10. Successors. This Agreement will inure to and be binding upon the Company's successors. The Company will require any successor to all or substantially all of the business and/or assets of the Company by sale, merger or consolidation (where the Company is not the surviving corporation), lease or otherwise, by agreement in form and substance satisfactory to Executive, to assume this Agreement expressly. This Agreement is not otherwise assignable by the Company or the Executive.

11. Amendment or Modification; Waiver. This Agreement may not be amended unless agreed to in writing by Executive and the Company. No waiver by either party of any breach of this Agreement will be deemed a waiver of a subsequent breach.

12. Severability. In the event that any provision of this Agreement is determined to be invalid or unenforceable, the remaining provisions shall remain in full force and effect to the fullest extent permitted by law.

13. Controlling Law. This Agreement will be controlled and interpreted pursuant to Massachusetts law, other than its choice of law principles.

14. Entire Agreement. This Agreement (including without limitation the Exhibits hereto) constitutes the entire agreement and supersedes conflicting terms in all prior agreements and undertakings, both written and oral, between Executive and the Company with respect to the subject matter hereof. Except as otherwise set forth herein, the terms and conditions of all other agreements with Executive, including without limitation all Restricted Stock Award Agreements and a Confidentiality and Inventions Agreement, shall continue in full force and effect.

15. Notices. Any notices required or permitted to be sent under this Agreement are to be delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to the Company:

Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472

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Lori Freedman 21 Swan Road Winchester, MA 01890

Either party may change its address for receiving notices by giving notice to the other party.

16. Release. Notwithstanding anything to the contrary contained in this Agreement, in order for Executive to be eligible for the severance benefits to be provided in accordance with this Agreement, Executive must sign (and not revoke within seven days of signing) a release of claims in the form attached hereto and marked Exhibit B.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]

In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Lori Freedman Name: Lori Freedman CONTROL DELIVERY SYSTEMS, INC. By: /s/ Michael J. Soja Name: Michael J. Soja Title: Vice President, Chief Financial Officer

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"Change of Control" means the occurrence of any of the following events:

(a) The acquisition by any Person or group of the ultimate beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of more than 50% of the then outstanding securities of the Company entitled to vote generally in the election of directors; excluding, however, the following: (i) any acquisition directly from the Company (other than any acquisition by virtue of the exercise of an exercise, conversion or exchange privilege unless the security being so exercised, converted or exchanged was itself acquired directly from the Company); (ii) any acquisition by the Company; (iii) any acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company or by any corporation controlled by the Company; (iv) any acquisition by the Executive, by an Executive Related Party (as defined in Exhibit A) or by a group of which the Executive is a member; or (v) any acquisition by any corporation pursuant to a transaction which complies with clauses (i), (ii) and (iii) of subsection (c) of this Exhibit A; or

(b) Individuals who, as of the date hereof, constitute the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election, by the Company's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or

 $(\ensuremath{\mathtt{v}})$  A reorganization, recapitalization, merger or consolidation (a "Corporate Transaction") of the Company, unless (i) securities representing more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the Company or such corporation after such Corporate Transaction) are beneficially owned subsequent to such Corporate Transaction by the Person or Persons who were the beneficial owners of the outstanding securities of the Company entitled to vote generally in the election of directors immediately prior to such Corporate Transaction, in substantially the same proportions as their ownership immediately prior to such Corporate Transaction; (ii) no Person (excluding any corporation resulting from such Corporate Transaction or any employee benefit plan (or related trust) of the Company or such corporation resulting from such Corporate Transaction) ultimately beneficially owns, directly or indirectly, more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the

Company or such corporation after such Corporate Transaction) except to the extent that such ownership existed prior to the Corporate Transaction; and (iii) at least a majority of the members of the board of directors of the corporation resulting from such Corporate Transaction were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Corporate Transaction; or

(c) The sale, transfer or other disposition of all or substantially all of the assets of the Company; or

(vi) Approval by the shareholders of the Company of a complete liquidation or dissolution of the Company.

For purposes of this definition, securities entitled to vote generally in the election of directors that are issuable upon exercise of an exercise, conversion or exchange privilege shall be deemed to be outstanding. In addition, for purposes of this definition the following terms have the meanings set forth below:

A Person will be deemed to be the "owner" of any securities of which such Person would be the "beneficial owner," as such term is defined in Rule 13d-3 promulgated by the Securities and Exchange Commission under the Exchange Act.

"Person" has the meaning used in Section 13(d) of the Exchange Act, except that "Person" does not include (i) the Executive, an Executive Related Party, or any group of which the Executive or Executive Related Party is a member, or (ii) the Company or a wholly owned subsidiary of the Company or an employee benefit plan (or related trust) of the Company or of a wholly owned subsidiary.

An "Executive Related Party" means any affiliate or associate of the Executive other than the Company or a subsidiary of the Company. The terms "affiliate" and "associate" have the meanings given in Rule 12b-2 under the Exchange Act; the term "registrant" in the definition of "associate" means, in this case, the Company.

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#### EXHIBIT B

## RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the Amended and Restated Change of Control Agreement between me and Control Delivery Systems, Inc. (the "Company") dated as of August 17, 2004 (the "Agreement"), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executives, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or any of its subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Articles of Incorporation or By-Laws of the Company or any of its subsidiaries or other affiliates.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its Affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the Company and that this

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Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature:					
Name	(please	print):			
Date	Signed:				

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### CONTROL DELIVERY SYSTEMS, INC. SEVERANCE AGREEMENT

AGREEMENT made this 20th day of February, 2004, by and between Paul Ashton ("Executive") and Control Delivery Systems, Inc. (the "Company").

Whereas, the Board of Directors of the Company (the "Board") recognizes that the possibility of additional layoffs and/or hibernation exists and that such possibility, and the uncertainty and questions which it may raise among certain key management personnel, may result in the departure or distraction of such management personnel to the detriment of the Company and its stockholders;

Whereas, the Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of certain key members of the Company's management, including Executive, to their duties, to assist the Board and the Company in maximizing the value of the Company, without distraction; and

Whereas, the Board wishes to induce Executive and other key members of management to remain in the employ of the Company and to assure them of fair severance should the employment of any of them terminate on or before October 7, 2005;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

- Severance Benefits. If on or before October 7, 2005 the Company terminates Executive's employment without Cause, or if Executive terminates his or her employment for Good Reason, the Company will provide severance benefits to Executive as follows:
  - a. All of the shares of restricted stock granted to Executive will automatically and immediately vest upon such termination.
  - b. All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable upon such termination and remain exercisable for a period of six months following such termination (or three months in the case of incentive stock options).
  - c. The Company will pay to Executive within 30 days of the termination a lump-sum cash amount equal to the sum of (x) an amount equal to six months' Base Salary plus (y) a pro-rated portion of the maximum bonus that would otherwise be payable in the year of termination, if any. "Base Salary" means Executive's base salary on the date of this agreement. For purposes of this Agreement, the maximum bonus payable in any year will be calculated assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the termination of Executive's employment, agreed on such targets or formulas. If no such targets or formulas have been set as of such termination date, then the

maximum bonus shall be deemed to be the actual bonus paid to  $\ensuremath{\mathsf{Executive}}$  during the preceding fiscal year.

- d. The Company will continue for a period of six months from the date of termination to provide Executive with the following benefits: (1) the Company's group medical plan, and (2) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company. To the extent that the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will pay Executive cash amounts equal to the cost the Company would have incurred to provide those benefits.
- 2. Definitions.
  - "Cause" means only (a) willful malfeasance or gross negligence in the a. performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.
  - "Good Reason" means (i) failure by the Company to maintain Executive b. in the positions of Chief Executive Officer and President including holding the title of and serving as Chief Executive Officer and President of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to provide Executive with Base Salary, benefits and other compensation (including without limitation bonus and other incentive compensation) Executive was receiving as of the date of this Agreement, or (iv) relocation of Executive's principal place of

work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.

- 3. Change of Control. Notwithstanding anything in this Agreement to the contrary (including without limitation Sections 1, 2 and 11 of this Agreement), if Executive is eligible for the benefits prescribed in the Change of Control Agreement between Executive and Company of even date herewith (the "Change of Control Agreement"), then Executive shall receive the benefits prescribed in the Change of Control Agreement and will not be eligible for benefits under this Agreement and the Company will have no obligation or liability to Executive under this Agreement.
- 4. Terminability of Employment. This Agreement does not constitute a contract of employment for a specific term. Employment with the Company is at-will. The Company may at any time terminate Executive's employment with the Company with or without notice or Cause.
- 5. Termination by the Company for Cause or by Executive Without Good Reason. If the Company terminates Executive's employment for Cause or if Executive terminates his employment other than for Good Reason, the Company will have no obligation or liability to Executive under this Agreement.
- 6. Withholding. All payments required to be made by the Company to Executive under this Agreement will be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as may be required by law.
- 7. Confidentiality, Non-Competition and Exclusivity. Executive further agrees to abide by all of the terms of the Confidentiality and Inventions Agreement dated as of July 27, 2001 ("Confidentiality and Inventions Agreement"). The parties recognize and agree that should the Company be required to pursue a claim against Executive under the Confidentiality and Inventions Agreement, the Company will likely be required to seek injunctive relief as well as damages at law. Accordingly, Section 8, Arbitration, will not apply to any action by the Company against Executive under the Confidentiality and Inventions Agreement.
- 8. Arbitration. Except as otherwise provided in Section 7, any dispute or controversy between the parties involving the construction or application of this Agreement, or any claim arising out of or relating to this Agreement, or any claim arising out of or relating to Executive's employment by the Company that is not resolved within ten days by the parties will be settled by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The Company and Executive agree that the arbitrator(s) will have no authority to award punitive or exemplary damages or so-called

consequential or remote damages such as damages for emotional distress. Any decision of the arbitrator(s) will be final and binding upon the parties. Either party may request that the arbitrator(s) submit written findings of fact and conclusions of law. The parties agree and understand that they hereby waive their rights to a jury trial of any dispute or controversy relating to the matters specified above in this Section.

- 9. Termination upon Death or Disability. If Executive ceases to be an employee of the Company as a result of death or disability, the Company will have no further obligation or liability to Executive under this Agreement. However, nothing in this Agreement is intended to interfere with the rights of Executive and his family or beneficiaries under other applicable plans, policies or arrangements of the Company applicable in the event of death or disability.
- 10. Rights of Survivors If Executive dies after becoming entitled to benefits under Section 1 following termination of employment but before all such benefits have been provided, all unpaid cash amounts will be paid to the beneficiary that has been designated by Executive in writing (the "beneficiary"), or if none, to Executive's estate.
- 11. Successors. This Agreement will inure to and be binding upon the Company's successors. The Company will require any successor to all or substantially all of the business and/or assets of the Company by sale, merger or consolidation (where the Company is not the surviving corporation), lease or otherwise, to assume this Agreement. This Agreement is not otherwise assignable by the Company or the Executive.
- 12. Amendment or Modification; Waiver. This Agreement may not be amended unless agreed to in writing by Executive and an expressly authorized officer of the Company. No waiver by either party of any breach of this Agreement will be deemed a waiver of a subsequent breach.
- 13. Controlling Law. This Agreement will be controlled and interpreted pursuant to Massachusetts law, other than its choice of law principles.
- 14. Entire Agreement. This Agreement constitutes the entire agreement and supersedes conflicting terms in all prior agreements and undertakings, both written and oral, between Executive and the Company with respect to the subject matter hereof. Except as otherwise set forth herein, the terms and conditions of all other agreements with Executive, including without limitation all Restricted Stock Award Agreements, Stock Option Grant Agreements, the Change of Control Agreement and the Confidentiality and Inventions Agreement, shall continue in full force and effect.
- 15. Notices. Any notices required or permitted to be sent under this Agreement shall be effective when delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to the Company:

Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472

If to Executive:

Paul Ashton 19 Brimmer Street Boston, MA 02108

Either party may change its address for receiving notices by giving notice to the other party.

16. Release. Notwithstanding anything to the contrary contained in this Agreement, in order for Executive to be eligible for the severance benefits to be provided in accordance with this Agreement, Executive must sign (and not revoke within seven days of signing) a release of claims in the form attached hereto and marked Exhibit A.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]

In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Paul Ashton Name: Paul Ashton

CONTROL DELIVERY SYSTEMS, INC.

By: /s/ Lori H. Freedman

Name: Lori H. Freedman Title: Vice President, Corporate Affairs & General Counsel

#### EXHIBIT A

## RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the Severance Agreement between me and Control Delivery Systems, Inc. (the "Company") dated as of February 20, 2004 (the "Agreement"), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executives, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or any of its subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Articles of Incorporation or By-Laws of the Company or any of its subsidiaries or other affiliates.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its Affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the

Company and that this Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature:

-----Name (please print):

Date Signed: -----

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### CONTROL DELIVERY SYSTEMS, INC. SEVERANCE AGREEMENT

AGREEMENT made this 20th day of February, 2004, by and between Michael J. Soja ("Executive") and Control Delivery Systems, Inc. (the "Company").

Whereas, the Board of Directors of the Company (the "Board") recognizes that the possibility of additional layoffs and/or hibernation exists and that such possibility, and the uncertainty and questions which it may raise among certain key management personnel, may result in the departure or distraction of such management personnel to the detriment of the Company and its stockholders;

Whereas, the Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of certain key members of the Company's management, including Executive, to their duties, to assist the Board and the Company in maximizing the value of the Company, without distraction; and

Whereas, the Board wishes to induce Executive and other key members of management to remain in the employ of the Company and to assure them of fair severance should the employment of any of them terminate on or before October 7, 2005;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

- Severance Benefits. If on or before October 7, 2005 the Company terminates Executive's employment without Cause, or if Executive terminates his or her employment for Good Reason, the Company will provide severance benefits to Executive as follows:
  - a. All of the shares of restricted stock granted to Executive will automatically and immediately vest upon such termination, including without limitation the following shares: 14,040 shares of restricted stock granted on May 28, 2003; 30,046 shares of restricted stock granted on October 7, 2003; 5,954 shares of restricted stock granted on October 7, 2003; 10,000 shares of restricted stock granted on October 7, 2003.
  - b. All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable upon such termination and remain exercisable for a period of six months following such termination (or three months in the case of incentive stock options).
  - c. The Company will pay to Executive within 30 days of the termination a lump-sum cash amount equal to the sum of (x) an amount equal to six months' Base Salary plus (y) a pro-rated portion of the maximum bonus that would otherwise be payable in the year of termination, if any. "Base Salary" means Executive's base salary on the date of this agreement. For purposes of this Agreement, the maximum bonus payable in any year will be calculated

assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the termination of Executive's employment, agreed on such targets or formulas. If no such targets or formulas have been set as of such termination date, then the maximum bonus shall be deemed to be the actual bonus paid to Executive during the preceding fiscal year.

- d. The Company will continue for a period of six months from the date of termination to provide Executive with the following benefits: (1) the Company's group medical plan, and (2) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company. To the extent that the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will pay Executive cash amounts equal to the cost the Company would have incurred to provide those benefits.
- 2. Definitions.
  - "Cause" means only (a) willful malfeasance or gross negligence in the а. performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.
  - b. "Good Reason" means (i) failure by the Company to maintain Executive in the position of Vice President, Chief Financial Officer including holding the title of and serving as Vice President, Chief Financial Officer of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly

after receipt of notice thereof given by Executive, (iii) failure by the Company to provide Executive with Base Salary, benefits and other compensation (including without limitation bonus and other incentive compensation) Executive was receiving as of the date of this Agreement, or (iv) relocation of Executive's principal place of work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.

- 3. Change of Control. Notwithstanding anything in this Agreement to the contrary (including without limitation Sections 1, 2 and 11 of this Agreement), if Executive is eligible for the benefits prescribed in the Change of Control Agreement between Executive and Company of even date herewith (the "Change of Control Agreement"), then Executive shall receive the benefits prescribed in the Change of Control Agreement and will not be eligible for benefits under this Agreement and the Company will have no obligation or liability to Executive under this Agreement.
- 4. Terminability of Employment. This Agreement does not constitute a contract of employment for a specific term. Employment with the Company is at-will. The Company may at any time terminate Executive's employment with the Company with or without notice or Cause.
- 5. Termination by the Company for Cause or by Executive Without Good Reason. If the Company terminates Executive's employment for Cause or if Executive terminates his employment other than for Good Reason, the Company will have no obligation or liability to Executive under this Agreement.
- 6. Withholding. All payments required to be made by the Company to Executive under this Agreement will be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as may be required by law.
- 7. Confidentiality, Non-Competition and Exclusivity. Executive further agrees to abide by all of the terms of the Employee Confidentiality, Proprietary Rights and Noncompetition Agreement dated as of February 26, 2001 ("Confidentiality and Inventions Agreement"). The parties recognize and agree that should the Company be required to pursue a claim against Executive under the Confidentiality and Inventions Agreement, the Company will likely be required to seek injunctive relief as well as damages at law. Accordingly, Section 8, Arbitration, will not apply to any action by the Company against Executive under the Confidentiality and Inventions Agreement.
- 8. Arbitration. Except as otherwise provided in Section 7, any dispute or controversy between the parties involving the construction or application of this Agreement, or any claim arising out of or relating to this Agreement, or any claim arising out of or relating to Executive's employment by the Company that is not resolved within ten

days by the parties will be settled by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The Company and Executive agree that the arbitrator(s) will have no authority to award punitive or exemplary damages or so-called consequential or remote damages such as damages for emotional distress. Any decision of the arbitrator(s) will be final and binding upon the parties. Either party may request that the arbitrator(s) submit written findings of fact and conclusions of law. The parties agree and understand that they hereby waive their rights to a jury trial of any dispute or controversy relating to the matters specified above in this Section.

- 9. Termination upon Death or Disability. If Executive ceases to be an employee of the Company as a result of death or disability, the Company will have no further obligation or liability to Executive under this Agreement. However, nothing in this Agreement is intended to interfere with the rights of Executive and his family or beneficiaries under other applicable plans, policies or arrangements of the Company applicable in the event of death or disability.
- 10. Rights of Survivors If Executive dies after becoming entitled to benefits under Section 1 following termination of employment but before all such benefits have been provided, all unpaid cash amounts will be paid to the beneficiary that has been designated by Executive in writing (the "beneficiary"), or if none, to Executive's estate.
- 11. Successors. This Agreement will inure to and be binding upon the Company's successors. The Company will require any successor to all or substantially all of the business and/or assets of the Company by sale, merger or consolidation (where the Company is not the surviving corporation), lease or otherwise, to assume this Agreement. This Agreement is not otherwise assignable by the Company or the Executive.
- 12. Amendment or Modification; Waiver. This Agreement may not be amended unless agreed to in writing by Executive and an expressly authorized officer of the Company. No waiver by either party of any breach of this Agreement will be deemed a waiver of a subsequent breach.
- 13. Controlling Law. This Agreement will be controlled and interpreted pursuant to Massachusetts law, other than its choice of law principles.
- 14. Entire Agreement. This Agreement constitutes the entire agreement and supersedes conflicting terms in all prior agreements and undertakings, both written and oral, between Executive and the Company with respect to the subject matter hereof. Except as otherwise set forth herein, the terms and conditions of all other agreements with Executive, including without limitation all Restricted Stock Award Agreements,

Stock Option Grant Agreements, the Change of Control Agreement and the Confidentiality and Inventions Agreement, shall continue in full force and effect.

15. Notices. Any notices required or permitted to be sent under this Agreement shall be effective when delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to the Company:

Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472

If to Executive:

Michael J. Soja 34 Musket Lane Sudbury, MA 01776

Either party may change its address for receiving notices by giving notice to the other party.

16. Release. Notwithstanding anything to the contrary contained in this Agreement, in order for Executive to be eligible for the severance benefits to be provided in accordance with this Agreement, Executive must sign (and not revoke within seven days of signing) a release of claims in the form attached hereto and marked Exhibit A.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]

In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Michael J. Soja Name: Michael J. Soja CONTROL DELIVERY SYSTEMS, INC. By: /s/ Paul Ashton Name: Paul Ashton Title: Chief Executive Officer & President

#### EXHIBIT A

## RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the Severance Agreement between me and Control Delivery Systems, Inc. (the "Company") dated as of February 20, 2004 (the "Agreement"), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executives, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or any of its subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Articles of Incorporation or By-Laws of the Company or any of its subsidiaries or other affiliates.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its Affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the

Company and that this Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature:

Name (please print): -----

Date Signed:

-----

### CONTROL DELIVERY SYSTEMS, INC. SEVERANCE AGREEMENT

AGREEMENT made this 20th day of February, 2004, by and between Lori Freedman ("Executive") and Control Delivery Systems, Inc. (the "Company").

Whereas, the Board of Directors of the Company (the "Board") recognizes that the possibility of additional layoffs and/or hibernation exists and that such possibility, and the uncertainty and questions which it may raise among certain key management personnel, may result in the departure or distraction of such management personnel to the detriment of the Company and its stockholders;

Whereas, the Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of certain key members of the Company's management, including Executive, to their duties, to assist the Board and the Company in maximizing the value of the Company, without distraction; and

Whereas, the Board wishes to induce Executive and other key members of management to remain in the employ of the Company and to assure them of fair severance should the employment of any of them terminate on or before October 7, 2005;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

- Severance Benefits. If on or before October 7, 2005 the Company terminates Executive's employment without Cause, or if Executive terminates his or her employment for Good Reason, the Company will provide severance benefits to Executive as follows:
  - a. All of the shares of restricted stock granted to Executive will automatically and immediately vest upon such termination, including without limitation the following shares: 11,700 shares of restricted stock granted on May 28, 2003; 24,046 shares of restricted stock granted on October 7, 2003; 5,954 shares of restricted stock granted on October 7, 2003; 10,000 shares of restricted stock granted on October 7, 2003.
  - b. All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable upon such termination and remain exercisable for a period of six months following such termination (or three months in the case of incentive stock options).
  - c. The Company will pay to Executive within 30 days of the termination a lump-sum cash amount equal to the sum of (x) an amount equal to six months' Base Salary plus (y) a pro-rated portion of the maximum bonus that would otherwise be payable in the year of termination, if any. "Base Salary" means Executive's base salary on the date of this agreement. For purposes of this Agreement, the maximum bonus payable in any year will be calculated

assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the termination of Executive's employment, agreed on such targets or formulas. If no such targets or formulas have been set as of such termination date, then the maximum bonus shall be deemed to be the actual bonus paid to Executive during the preceding fiscal year.

- d. The Company will continue for a period of six months from the date of termination to provide Executive with the following benefits: (1) the Company's group medical plan, and (2) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company. To the extent that the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will pay Executive cash amounts equal to the cost the Company would have incurred to provide those benefits.
- 2. Definitions.
  - "Cause" means only (a) willful malfeasance or gross negligence in the а. performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.
  - b. "Good Reason" means (i) failure by the Company to maintain Executive in the positions of Vice President, Corporate Affairs, General Counsel and Secretary including holding the title of and serving as Vice President, Corporate Affairs, General Counsel and Secretary of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and

which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to provide Executive with Base Salary, benefits and other compensation (including without limitation bonus and other incentive compensation) Executive was receiving as of the date of this Agreement, or (iv) relocation of Executive's principal place of work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.

- 3. Change of Control. Notwithstanding anything in this Agreement to the contrary (including without limitation Sections 1, 2 and 11 of this Agreement), if Executive is eligible for the benefits prescribed in the Amended and Restated Change of Control Agreement between Executive and Company dated December 18, 2003 (the "Change of Control Agreement"), then Executive shall receive the benefits prescribed in the Change of Control Agreement and will not be eligible for benefits under this Agreement and the Company will have no obligation or liability to Executive under this Agreement.
- 4. Terminability of Employment. This Agreement does not constitute a contract of employment for a specific term. Employment with the Company is at-will. The Company may at any time terminate Executive's employment with the Company with or without notice or Cause.
- 5. Termination by the Company for Cause or by Executive Without Good Reason. If the Company terminates Executive's employment for Cause or if Executive terminates his employment other than for Good Reason, the Company will have no obligation or liability to Executive under this Agreement.
- 6. Withholding. All payments required to be made by the Company to Executive under this Agreement will be subject to the withholding of such amounts, if any, relating to tax and other payroll deductions as may be required by law.
- 7. Confidentiality, Non-Competition and Exclusivity. Executive further agrees to abide by all of the terms of the Employee Confidentiality, Proprietary Rights and Noncompetition Agreement dated as of October 1, 2001 ("Confidentiality and Inventions Agreement"). The parties recognize and agree that should the Company be required to pursue a claim against Executive under the Confidentiality and Inventions Agreement, the Company will likely be required to seek injunctive relief as well as damages at law. Accordingly, Section 8, Arbitration, will not apply to any action by the Company against Executive under the Confidentiality and Inventions Agreement.
- Arbitration. Except as otherwise provided in Section 7, any dispute or controversy between the parties involving the construction or application of this Agreement, or any claim arising out of or relating to this Agreement, or any claim arising out of or

relating to Executive's employment by the Company that is not resolved within ten days by the parties will be settled by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect, and judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The Company and Executive agree that the arbitrator(s) will have no authority to award punitive or exemplary damages or so-called consequential or remote damages such as damages for emotional distress. Any decision of the arbitrator(s) will be final and binding upon the parties. Either party may request that the arbitrator(s) submit written findings of fact and conclusions of law. The parties agree and understand that they hereby waive their rights to a jury trial of any dispute or controversy relating to the matters specified above in this Section.

- 9. Termination upon Death or Disability. If Executive ceases to be an employee of the Company as a result of death or disability, the Company will have no further obligation or liability to Executive under this Agreement. However, nothing in this Agreement is intended to interfere with the rights of Executive and his family or beneficiaries under other applicable plans, policies or arrangements of the Company applicable in the event of death or disability.
- 10. Rights of Survivors If Executive dies after becoming entitled to benefits under Section 1 following termination of employment but before all such benefits have been provided, all unpaid cash amounts will be paid to the beneficiary that has been designated by Executive in writing (the "beneficiary"), or if none, to Executive's estate.
- 11. Successors. This Agreement will inure to and be binding upon the Company's successors. The Company will require any successor to all or substantially all of the business and/or assets of the Company by sale, merger or consolidation (where the Company is not the surviving corporation), lease or otherwise, to assume this Agreement. This Agreement is not otherwise assignable by the Company or the Executive.
- 12. Amendment or Modification; Waiver. This Agreement may not be amended unless agreed to in writing by Executive and an expressly authorized officer of the Company. No waiver by either party of any breach of this Agreement will be deemed a waiver of a subsequent breach.
- 13. Controlling Law. This Agreement will be controlled and interpreted pursuant to Massachusetts law, other than its choice of law principles.
- 14. Entire Agreement. This Agreement constitutes the entire agreement and supersedes conflicting terms in all prior agreements and undertakings, both written and oral, between Executive and the Company with respect to the subject matter hereof. Except as otherwise set forth herein, the terms and conditions of all other agreements with Executive, including without limitation all Restricted Stock Award Agreements,

Stock Option Grant Agreements, the Change of Control Agreement and the Confidentiality and Inventions Agreement, shall continue in full force and effect.

15. Notices. Any notices required or permitted to be sent under this Agreement shall be effective when delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to the Company:

Control Delivery Systems, Inc. 400 Pleasant Street Watertown, MA 02472

If to Executive:

Lori Freedman 21 Swan Road Winchester, MA 01890

Either party may change its address for receiving notices by giving notice to the other party.

16. Release. Notwithstanding anything to the contrary contained in this Agreement, in order for Executive to be eligible for the severance benefits to be provided in accordance with this Agreement, Executive must sign (and not revoke within seven days of signing) a release of claims in the form attached hereto and marked Exhibit A.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]

In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Lori H. Freedman Name: Lori H. Freedman CONTROL DELIVERY SYSTEMS, INC. By: /s/ Paul Ashton Name: Paul Ashton Title: Chief Executive Officer & President

#### EXHIBIT A

## RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the Severance Agreement between me and Control Delivery Systems, Inc. (the "Company") dated as of February 20, 2004 (the "Agreement"), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executives, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or any of its subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Articles of Incorporation or By-Laws of the Company or any of its subsidiaries or other affiliates.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its Affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the

Company and that this Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature:

-----Name (please print):

Date Signed: -----

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# FIRST AMENDMENT CONTROL DELIVERY SYSTEMS, INC. SEVERANCE AGREEMENT

This First Amendment to Severance Agreement (this "Amendment") made this 17th day of August, 2004 (the "Amendment Effective Date"), by and between Paul Ashton ("Executive") and Control Delivery Systems, Inc. (the "Company").

Reference is made to (a) that certain Severance Agreement dated February 20, 2004, by and between Executive and the Company (the "Severance Agreement"), and (b) that certain Control Delivery Systems, Inc. 2001 Incentive Plan Restricted Stock Award Agreement dated August 16, 2004 between Executive and the Company (the "August 2004 Restricted Stock Award Agreement").

Whereas, the Board of Directors of the Company (the "Board") has determined that Executive's salary should be reduced below Base Salary;

Whereas, Executive has agreed to such reduction in salary under the terms and conditions set forth in this Amendment;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

- 1. Restricted Stock.
  - a. Section 11 of the August 2004 Restricted Stock Award Agreement is hereby deleted in its entirety and the following is substituted in place thereof: "Right of Repurchase of Vested Shares. Notwithstanding anything in this Agreement to the contrary, the Company agrees that it will not exercise any right that the Company has to purchase, repurchase or reacquire all or any part of Employee's Vested Shares."
- Bonus. Subject to the occurrence of the Bonus Date and provided that Executive is employed by the Company on the Bonus Date, Executive shall be eligible for a bonus equal to Bonus Amount.

"Bonus Amount" means that amount equal to the product of (a) \$301.37 multiplied by (b) the number of calendar days that have elapsed during the period beginning on August 16, 2004 and ending on the Bonus Date.

"Bonus Date" means the earliest date that the Board reasonably determines that the Company has the financial resources to pay Executive a bonus equal to the Bonus Amount.

The parties acknowledge and agree that any obligation to pay a bonus is solely that of the Company and that none of the directors or officers of the Company shall have any personal liability with respect thereto.

- 3. Amendment to Section 1 of Severance Agreement. Section 1 of the Severance Agreement is hereby deleted in its entirety and the following is substituted in place thereof:
  - a. "1. Severance Benefits.
    - i. Severance Benefits in the event of termination on or before December 31, 2006. If on or before December 31, 2006, the Company terminates Executive's employment without Cause, or Executive terminates his or her employment for Good Reason, the Company will provide severance benefits to Executive as follows:
      - Notwithstanding anything to the contrary in any agreement between Executive and Company, including without limitation Section 6 of the August 2004 Restricted Stock Award Agreement, all unvested shares of restricted stock granted to Executive will automatically and immediately vest on the Separation Date and no longer be subject to forfeiture, including without limitation the following shares: 20,000 shares of restricted stock granted on August 16, 2004.
      - All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable on the Separation Date and remain exercisable for a period of six months following the Separation Date (or three months in the case of incentive stock options).
      - 3. The Company will pay to Executive a lump-sum cash amount equal to the Severance Payment within 30 days following the later of (a) the Separation Date, and (b) the date Executive delivers to Company a release of claims in accordance with Section 16 of this Agreement. Notwithstanding the foregoing, in the event the Separation Date occurs after March 31, 2005, the Company shall have the right to defer payment of the Severance Payment until the Deferment Date, provided that the Severance Payment will accrue simple interest at the rate of 3 % per year, payable on the Deferment Date. The parties acknowledge and agree that the obligation to pay the Severance Payment is solely that of the Company and that none of the directors or officers of the Company shall have any personal liability with respect thereto.

- 4. The Company will continue for a period of six months from the Separation Date to provide Executive with the following benefits: (1) the Company's group medical plan, and (2) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company. To the extent that the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will pay Executive cash amounts equal to the cost the Company would have incurred to provide those benefits.
- Amendment to Section 2 of the Severance Agreement. Section 2 of the Severance Agreement is hereby deleted in its entirety and the following is substituted in place thereof:
  - a. "2. Definitions.
    - i. "Applicable Base Salary" means: (a) for that period beginning August 16, 2004 and ending on that date which is 30 days following the Base Salary and Bonus Date, \$140,000 and (b) for that period beginning on that date which is 31 days following the Base Salary and Bonus Date and ending on December 31, 2006, Base Salary.
    - ii. "Base Salary" means \$250,000 provided that in the event the Board in its sole discretion increases Executive's Base Salary above \$250,000, the Base Salary as so increased will be referred to as "Base Salary."
    - iii. "Base Salary and Bonus Date" means the first date on which both of the following conditions are met (a) the sum of all royalty payments received by the Company from Bausch & Lomb after December 31, 2004 under that certain Amended and Restated License Agreement between the Company and Bausch & Lomb dated December 9, 2003 equals five million dollars (\$5,000,000), and (b) the sum of (i) cash, cash equivalents and short term investments, plus (ii) accounts receivable equals five million dollars (\$5,000,000).
    - iv. "Bonus Amount" means that amount equal to the product of (a) \$301.37 multiplied by (b) the number of calendar days that have elapsed during the period beginning on August 16, 2004 and ending on the Base Salary and Bonus Date.
    - v. "Cause" means only (a) willful malfeasance or gross negligence in the performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for

Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.

- vi. "Deferment Date" means the earliest to occur of the date (a) the Company files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it, (b) the sum of all amounts paid to the Company from any source (including without limitation from Bausch & Lomb, financing sources or under any new or existing license or other commercial arrangement) after March 31, 2005 equals two million dollars (\$2,000,000) and (c) December 31, 2005.
- vii. "Good Reason" means (i) failure by the Company to maintain Executive in the positions of Chief Executive Officer and President including holding the title of and serving as Chief Executive Officer and President of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to (a) provide Executive with the Applicable Base Salary, (b) pay Executive a bonus equal to Bonus Amount within thirty (30) days following the Base Salary and Bonus Date, or (c) provide Executive with the benefits and other compensation (including without limitation bonus and other incentive compensation) Executive was receiving as of the date of this Agreement, or (iv) relocation of Executive's principal place of work to

a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.

- viii. "Maximum Bonus" means the maximum bonus payable in any year and is calculated assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the Separation Date, agreed on such targets or formulas. If no such targets or formulas have been set as of the Separation Date, then the maximum bonus shall be deemed to be the actual bonus paid to Executive during the preceding fiscal year. Notwithstanding anything herein to the contrary, Maximum Bonus shall not include the Bonus Amount.
- ix. "Reduced Base Salary" means \$140,000.
- x. "Separation Date" means the date the Employee's employment with the Company ends.
- xi. "Severance Payment" means the sum of (x) an amount equal to twelve months' Base Salary plus (y) a pro-rated portion of the Maximum Bonus that would otherwise be payable in the year that the Separation Date occurs, if any.
- Remainder of Severance Agreement Unaffected. In all other respects, the provisions of the Severance Agreement shall remain in full force and effect.

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In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Paul Ashton Name: Paul Ashton CONTROL DELIVERY SYSTEMS, INC. By: /s/ Lori Freedman Name: Lori Freedman Title: VP, Corporate Affairs & General Counsel

## FIRST AMENDMENT CONTROL DELIVERY SYSTEMS, INC. SEVERANCE AGREEMENT

This First Amendment to Severance Agreement (this "Amendment") made this 17th day of August, 2004 (the "Amendment Effective Date"), by and between Michael J. Soja ("Executive") and Control Delivery Systems, Inc. (the "Company").

Reference is made to (a) that certain Severance Agreement dated February 20, 2004, by and between Executive and the Company (the "Severance Agreement"), (b) that certain Control Delivery Systems, Inc. 2001 Incentive Plan Restricted Stock Award Agreement dated October 7, 2003 between Executive and the Company and that certain Control Delivery Systems, Inc. 1997 Incentive Plan Restricted Stock Award Agreement dated October 7, 2003 between Executive and the Company (collectively, the "October 2003 Restricted Stock Award Agreements"), (c) that certain Control Delivery Systems, Inc. 2001 Incentive Plan Restricted Stock Award Agreement dated May 28, 2003 between Executive and the Company (the "May 2003 Restricted Stock Award Agreement"), and (d) that certain Control Delivery Systems, Inc. 2001 Incentive Plan Restricted August 16, 2004 between Executive and the Company (the "August 2004 Restricted Stock Award Agreement").

Whereas, the Board of Directors of the Company (the "Board") has determined that Executive's salary should be reduced below Base Salary;

Whereas, Executive has agreed to such reduction in salary under the terms and conditions set forth in this Amendment;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

1. Restricted Stock.

- a. Notwithstanding anything to the contrary in the October 2003 Restricted Stock Award Agreements, including without limitation Section 6 of such agreements, and notwithstanding anything to the contrary in the May 2003 Restricted Stock Award Agreement, including without limitation Section 7 of such agreement, all of the shares of restricted stock granted prior to August 16, 2004 shall automatically and immediately vest on the Amendment Effective Date and no longer be subject to forfeiture, including without limitation the following shares: 14,040 shares of restricted stock granted on May 28, 2003; 30,046 shares of restricted stock granted on October 7, 2003; 5,954 shares of restricted stock granted on October 7, 2003; 10,000 shares of restricted stock granted on October 7, 2003.
- b. Section 11 of the October 2003 Restricted Stock Award Agreements, Section 11 of the August 2004 Restricted Stock Award Agreement and Section 12 of

the May 2003 Restricted Stock Award Agreement are each hereby deleted in their entirety and the following is substituted in place thereof: "Right of Repurchase of Vested Shares. Notwithstanding anything in this Agreement to the contrary, the Company agrees that it will not exercise any right that the Company has to purchase, repurchase or reacquire all or any part of Employee's Vested Shares."

 Bonus. Subject to the occurrence of the Bonus Date and provided that Executive is employed by the Company on the Bonus Date, Executive shall be eligible for a bonus equal to Bonus Amount.

"Bonus Amount" means that amount equal to the product of (a) \$335.61 multiplied by (b) the number of calendar days that have elapsed during the period beginning on August 16, 2004 and ending on the Bonus Date.

"Bonus Date" means the earliest date that the Board reasonably determines that the Company has the financial resources to pay Executive a bonus equal to the Bonus Amount.

The parties acknowledge and agree that any obligation to pay a bonus is solely that of the Company and that none of the directors or officers of the Company shall have any personal liability with respect thereto.

- 3. Amendment to Section 1 of Severance Agreement. Section 1 of the Severance Agreement is hereby deleted in its entirety and the following is substituted in place thereof:
  - a. "1. Severance Benefits.
    - i. Severance Benefits in the event of termination on or before December 31, 2006. If on or before December 31, 2006, the Company terminates Executive's employment without Cause, or Executive terminates his or her employment for Good Reason, the Company will provide severance benefits to Executive as follows:
      - Notwithstanding anything to the contrary in any agreement between Executive and Company, including without limitation Section 6 of the August 2004 Restricted Stock Award Agreement, all unvested shares of restricted stock granted to Executive will automatically and immediately vest on the Separation Date and no longer be subject to forfeiture, including without limitation the following shares: 20,000 shares of restricted stock granted on August 16, 2004.
      - All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable on the Separation Date and remain exercisable for a period of six

months following the Separation Date (or three months in the case of incentive stock options).

- 3. The Company will pay to Executive a lump-sum cash amount equal to the Severance Payment within 30 days following the later of (a) the Separation Date, and (b) the date Executive delivers to Company a release of claims in accordance with Section 16 of this Agreement. Notwithstanding the foregoing, in the event the Separation Date occurs after March 31, 2005, the Company shall have the right to defer payment of the Severance Payment until the Deferment Date, provided that the Severance Payment will accrue simple interest at the rate of 3 % per year, payable on the Deferment Date. The parties acknowledge and agree that the obligation to pay the Severance Payment is solely that of the Company shall have any personal liability with respect thereto.
- 4. The Company will continue for a period of six months from the Separation Date to provide Executive with the following benefits: (1) the Company's group medical plan, and (2) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company. To the extent that the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will pay Executive cash amounts equal to the cost the Company would have incurred to provide those benefits.
- 4. Amendment to Section 2 of the Severance Agreement. Section 2 of the Severance Agreement is hereby deleted in its entirety and the following is substituted in place thereof:

a. "2. Definitions.

- i. "Applicable Base Salary" means: (a) for that period beginning August 16, 2004 and ending on that date which is 30 days following the Base Salary and Bonus Date, \$150,000 and (b) for that period beginning on that date which is 31 days following the Base Salary and Bonus Date and ending on December 31, 2006, Base Salary.
- ii. "Base Salary" means \$272,497, provided that in the event the Board in its sole discretion increases Executive's Base Salary above \$272,497, the Base Salary as so increased will be referred to as "Base Salary."
- iii. "Base Salary and Bonus Date" means the first date on which both of the following conditions are met (a) the sum of all royalty payments

received by the Company from Bausch & Lomb after December 31, 2004 under that certain Amended and Restated License Agreement between the Company and Bausch & Lomb dated December 9, 2003 equals five million dollars (\$5,000,000), and (b) the sum of (i) cash, cash equivalents and short term investments, plus (ii) accounts receivable equals five million dollars (\$5,000,000).

- iv. "Bonus Amount" means that amount equal to the product of (a) \$335.61 multiplied by (b) the number of calendar days that have elapsed during the period beginning on August 16, 2004 and ending on the Base Salary and Bonus Date.
- "Cause" means only (a) willful malfeasance or gross negligence in v. the performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.
- vi. "Deferment Date" means the earliest to occur of the date (a) the Company files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it, (b) the sum of all amounts paid to the Company from any source (including without limitation from Bausch & Lomb, financing sources or under any new or existing license or other commercial arrangement) after March 31, 2005 equals two million dollars (\$2,000,000) and (c) December 31, 2005.

- vii. "Good Reason" means (i) failure by the Company to maintain Executive in the position of Vice President, Chief Financial Officer including holding the title of and serving as Vice President, Chief Financial Officer of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to (a) provide Executive with the Applicable Base Salary, (b) pay Executive a bonus equal to Bonus Amount within thirty (30) days following the Base Salary and Bonus Date, or (c) provide Executive with the benefits and other compensation (including without limitation bonus and other incentive compensation) Executive was receiving as of the date of this Agreement, or (iv) relocation of Executive's principal place of work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.
- viii. "Maximum Bonus" means the maximum bonus payable in any year and is calculated assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the Separation Date, agreed on such targets or formulas. If no such targets or formulas have been set as of the Separation Date, then the maximum bonus shall be deemed to be the actual bonus paid to Executive during the preceding fiscal year. Notwithstanding anything herein to the contrary, Maximum Bonus shall not include the Bonus Amount.
- ix. "Reduced Base Salary" means \$150,000.
- x. "Separation Date" means the date the Employee's employment with the Company ends.
- xi. "Severance Payment" means the sum of (x) an amount equal to six months' Base Salary plus (y) a pro-rated portion of the Maximum Bonus that would otherwise be payable in the year that the Separation Date occurs, if any.
- Remainder of Severance Agreement Unaffected. In all other respects, the provisions of the Severance Agreement shall remain in full force and effect.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK.]

In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Michael J. Soja Name: Michael J. Soja CONTROL DELIVERY SYSTEMS, INC. By: /s/ Paul Ashton Name: Paul Ashton Title: Chief Executive Officer & President

## FIRST AMENDMENT CONTROL DELIVERY SYSTEMS, INC. SEVERANCE AGREEMENT

This First Amendment to Severance Agreement (this "Amendment") made this 17th day of August, 2004 (the "Amendment Effective Date"), by and between Lori H. Freedman ("Executive") and Control Delivery Systems, Inc. (the "Company").

Reference is made to (a) that certain Severance Agreement dated February 20, 2004, by and between Executive and the Company (the "Severance Agreement"), (b) that certain Control Delivery Systems, Inc. 2001 Incentive Plan Restricted Stock Award Agreement dated October 7, 2003 between Executive and the Company and that certain Control Delivery Systems, Inc. 1997 Incentive Plan Restricted Stock Award Agreement dated October 7, 2003 between Executive and the Company (collectively, the "October 2003 Restricted Stock Award Agreements"), (c) that certain Control Delivery Systems, Inc. 2001 Incentive Plan Restricted Stock Award Agreement dated May 28, 2003 between Executive and the Company (the "May 2003 Restricted Stock Award Agreement"), and (d) that certain Control Delivery Systems, Inc. 2001 Incentive Plan Restricted Stock Award Agreement dated August 16, 2004 between Executive and the Company (the "August 2004 Restricted Stock Award Agreement").

Whereas, the Board of Directors of the Company (the "Board") has determined that Executive's salary should be reduced below Base Salary;

Whereas, Executive has agreed to such reduction in salary under the terms and conditions set forth in this Amendment;

NOW, THEREFORE, in consideration of the premises and the mutual promises, terms and conditions contained herein, the parties hereto agree as follows:

1. Restricted Stock.

- a. Notwithstanding anything to the contrary in the October 2003 Restricted Stock Award Agreements, including without limitation Section 6 of such agreements, and notwithstanding anything to the contrary in the May 2003 Restricted Stock Award Agreement, including without limitation Section 7 of such agreement, all of the shares of restricted stock granted prior to August 16, 2004 shall automatically and immediately vest on the Amendment Effective Date and no longer be subject to forfeiture, including without limitation the following shares: 11,700 shares of restricted stock granted on May 28, 2003; 24,046 shares of restricted stock granted on October 7, 2003; 5,954 shares of restricted stock granted on October 7, 2003; 10,000 shares of restricted stock granted on October 7, 2003.
- b. Section 11 of the October 2003 Restricted Stock Award Agreements, Section 11 of the August 2004 Restricted Stock Award Agreement and Section 12 of

the May 2003 Restricted Stock Award Agreement are each hereby deleted in their entirety and the following is substituted in place thereof: "Right of Repurchase of Vested Shares. Notwithstanding anything in this Agreement to the contrary, the Company agrees that it will not exercise any right that the Company has to purchase, repurchase or reacquire all or any part of Employee's Vested Shares."

 Bonus. Subject to the occurrence of the Bonus Date and provided that Executive is employed by the Company on the Bonus Date, Executive shall be eligible for a bonus equal to Bonus Amount.

"Bonus Amount" means that amount equal to the product of (a) \$124.28 multiplied by (b) the number of calendar days that have elapsed during the period beginning on August 16, 2004 and ending on the Bonus Date.

"Bonus Date" means the earliest date that the Board reasonably determines that the Company has the financial resources to pay Executive a bonus equal to the Bonus Amount.

The parties acknowledge and agree that any obligation to pay a bonus is solely that of the Company and that none of the directors or officers of the Company shall have any personal liability with respect thereto.

- 3. Amendment to Section 1 of Severance Agreement. Section 1 of the Severance Agreement is hereby deleted in its entirety and the following is substituted in place thereof:
  - a. "1. Severance Benefits.
    - i. Severance Benefits in the event of termination on or before December 31, 2006. If on or before December 31, 2006, the Company terminates Executive's employment without Cause, or Executive terminates his or her employment for Good Reason, the Company will provide severance benefits to Executive as follows:
      - Notwithstanding anything to the contrary in any agreement between Executive and Company, including without limitation Section 6 of the August 2004 Restricted Stock Award Agreement, all unvested shares of restricted stock granted to Executive will automatically and immediately vest on the Separation Date and no longer be subject to forfeiture, including without limitation the following shares: 20,000 shares of restricted stock granted on August 16, 2004.
      - All options to purchase Company stock held by Executive will automatically and immediately vest and become exercisable on the Separation Date and remain exercisable for a period of six

months following the Separation Date (or three months in the case of incentive stock options).

- 3. The Company will pay to Executive a lump-sum cash amount equal to the Severance Payment within 30 days following the later of (a) the Separation Date, and (b) the date Executive delivers to Company a release of claims in accordance with Section 16 of this Agreement. Notwithstanding the foregoing, in the event the Separation Date occurs after March 31, 2005, the Company shall have the right to defer payment of the Severance Payment until the Deferment Date, provided that the Severance Payment will accrue simple interest at the rate of 3 % per year, payable on the Deferment Date. The parties acknowledge and agree that the obligation to pay the Severance Payment is solely that of the Company shall have any personal liability with respect thereto.
- 4. The Company will continue for a period of six months from the Separation Date to provide Executive with the following benefits: (1) the Company's group medical plan, and (2) life insurance arrangements or disability plan arrangements provided to executive-level employees of the Company. To the extent that the Company is unable to provide such benefits to Executive under its existing plans and arrangements, it will pay Executive cash amounts equal to the cost the Company would have incurred to provide those benefits.
- 4. Amendment to Section 2 of the Severance Agreement. Section 2 of the Severance Agreement is hereby deleted in its entirety and the following is substituted in place thereof:

a. "2. Definitions.

- i. "Applicable Base Salary" means: (a) for that period beginning August 16, 2004 and ending on that date which is 30 days following the Base Salary and Bonus Date, \$140,000 and (b) for that period beginning on that date which is 31 days following the Base Salary and Bonus Date and ending on December 31, 2006, Base Salary.
- ii. "Base Salary" means \$185,361 provided that in the event the Board in its sole discretion increases Executive's Base Salary above \$185,361, the Base Salary as so increased will be referred to as "Base Salary."
- iii. "Base Salary and Bonus Date" means the first date on which both of the following conditions are met (a) the sum of all royalty payments

received by the Company from Bausch & Lomb after December 31, 2004 under that certain Amended and Restated License Agreement between the Company and Bausch & Lomb dated December 9, 2003 equals five million dollars (\$5,000,000), and (b) the sum of (i) cash, cash equivalents and short term investments, plus (ii) accounts receivable equals five million dollars (\$5,000,000).

- iv. "Bonus Amount" means that amount equal to the product of (a) \$124.28 multiplied by (b) the number of calendar days that have elapsed during the period beginning on August 16, 2004 and ending on the Base Salary and Bonus Date.
- "Cause" means only (a) willful malfeasance or gross negligence in v. the performance by Executive of his or her duties, resulting in material harm to the Company, (b) fraud or dishonesty by Executive with respect to the Company, or (c) Executive's conviction of any felony involving deception, fraud or moral turpitude. The Company may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause and of his or her right to a hearing by the Board, (ii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iii) giving Executive 30 days' written notice of the results of the hearing, which shall require a vote of a majority of the Directors then in office other than Executive. For purposes of this definition of Cause, no act or omission shall be considered to have been "willful" unless it was not in good faith and Executive had knowledge at the time that the act or omission was not in the best interest of the Company. Any act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of counsel of the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interest of the Company. Cause shall not include willful failure due to incapacity resulting from physical or mental illness or any actual or anticipated failure after Notice of Termination for Good Reason.
- vi. "Deferment Date" means the earliest to occur of the date (a) the Company files for protection under the bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it, (b) the sum of all amounts paid to the Company from any source (including without limitation from Bausch & Lomb, financing sources or under any new or existing license or other commercial arrangement) after March 31, 2005 equals two million dollars (\$2,000,000) and (c) December 31, 2005.

- vii. "Good Reason" means (i) failure by the Company to maintain Executive in the positions of Vice President, Corporate Affairs, General Counsel and Secretary including holding the title of and serving as Vice President, Corporate Affairs, General Counsel and Secretary of the Company and having responsibility for performing all duties typically undertaken by such offices or assignment to Executive of duties materially inconsistent with such positions, (ii) the diminution in any material respect of Executive's positions or authority, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by Executive, (iii) failure by the Company to (a) provide Executive with the Applicable Base Salary, (b) pay Executive a bonus equal to Bonus Amount within thirty (30) days following the Base Salary and Bonus Date, or (c) provide Executive with the benefits and other compensation (including without limitation bonus and other incentive compensation) Executive was receiving as of the date of this Agreement, or (iv) relocation of Executive's principal place of work to a location more than 30 miles from its current location without Executive's consent. For purposes of this definition of Good Reason, "Company" means Control Delivery Systems and any successor of Control Delivery Systems, provided if any such successor has a parent, then Company shall mean the ultimate parent corporation.
- viii. "Maximum Bonus" means the maximum bonus payable in any year and is calculated assuming all bonus targets or formulas for determining the bonus in such year had been met if Executive and Board had, prior to the Separation Date, agreed on such targets or formulas. If no such targets or formulas have been set as of the Separation Date, then the maximum bonus shall be deemed to be the actual bonus paid to Executive during the preceding fiscal year. Notwithstanding anything herein to the contrary, Maximum Bonus shall not include the Bonus Amount.
- ix. "Reduced Base Salary" means \$140,000.
- x. "Separation Date" means the date the Employee's employment with the Company ends.
- xi. "Severance Payment" means the sum of (x) an amount equal to six months' Base Salary plus (y) a pro-rated portion of the Maximum Bonus that would otherwise be payable in the year that the Separation Date occurs, if any.

 Remainder of Severance Agreement Unaffected. In all other respects, the provisions of the Severance Agreement shall remain in full force and effect.

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In witness whereof, the parties hereto have executed this Agreement as of the date first set forth above.

By: /s/ Lori H. Freedman Name: Lori H. Freedman CONTROL DELIVERY SYSTEMS, INC. By: /s/ Paul Ashton Name: Paul Ashton Title: Chief Executive Officer & President

# CONTROL DELIVERY SYSTEMS, INC. 2001 INCENTIVE PLAN

#### Restricted Stock Award Agreement

The undersigned employee ("Employee") has been granted an award (the "Award") of restricted stock from Control Delivery Systems, Inc. (the "Company") under the 2001 Incentive Plan (the "Plan"), subject to the terms set forth below and in the Plan, a copy of which as currently in effect has been delivered to Employee. In consideration of the grant of the Award, the Employee agrees with the Company as follows:

1. Effective Date. This Agreement shall take effect as of the date of grant of the Award, as indicated on the signature page hereof.

2. Shares Subject to Award. The Award consists of the number of shares set forth on the signature page hereof (the "Shares") of common stock of the Company ("Stock"). Employee's rights to the Shares are subject to the restrictions described in this Agreement and the Plan in addition to such other restrictions, if any, as may be imposed by law.

3. Meaning of Certain Terms. Except as otherwise expressly provided, all terms used herein shall have the same meaning as in the Plan. The term "vest" as used herein with respect to any Share means the lapsing of the restrictions described herein with respect to such Share.

4. Nontransferability of Shares. The Shares cannot be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until they have vested, and then only as provided below and in the Plan.

5. Forfeiture Risk. If Employee ceases to be employed by the Company and its subsidiaries for any reason, including death, any then outstanding and unvested Shares shall be automatically and immediately forfeited. Employee hereby (i) appoints the Company as the attorney-in-fact of Employee to take such actions as may be necessary or appropriate to effectuate a transfer of the record ownership of any such shares that are unvested and forfeited hereunder, (ii) agrees to deliver to the Company, as a precondition to the issuance of any certificate or certificates with respect to unvested Shares hereunder, one or more stock powers, endorsed in blank, with respect to such Shares, and (iii) agrees to sign such other powers and take such other actions as the Company may reasonably request to accomplish the transfer or forfeiture of any unvested Shares that are forfeited hereunder.

6. Vesting of Shares. The Shares shall vest in accordance with the provisions of this Paragraph 6 and applicable provisions of the Plan (if not earlier in accordance with the Plan, including Section 6 of the Plan), as follows:

100% of the Shares will vest on the earlier to occur of:

- October 7, 2005; or
- a Liquidity Event Date (as defined below).

PAGE 1 OF 9

Notwithstanding the foregoing, in the event that a Liquidity Event Date that relates to an initial public offering occurs on or before October 7, 2005, 100% of the Shares shall vest on that date which is the six-month anniversary of the closing of the initial public offering.

Any securities of the Company or any other entity, and any cash and other consideration, into which the Shares are converted or for which they are exchanged, by reason of a merger, consolidation, sale of assets, reorganization or other transaction, shall vest (by their terms or through the use of an escrow, a commitment to deliver in the future or such other device as is determined by the administrator of the Plan) on the same terms as the Shares from which they were converted or for which they were exchanged.

A "Liquidity Event" means any public offering, merger, consolidation, sale of assets, reorganization or other transaction in or as a result of which the Stock of the Company (or the stock or other securities into or for which such Stock is converted or exchanged) are or become registered under the Securities Exchange Act of 1934 or are converted into or exchanged for cash. "Liquidity Event Date" shall mean the date of the closing of a Liquidity Event.

Notwithstanding the foregoing, no Shares shall vest on any vesting date specified above unless Employee is then, and since the date of grant has continuously been, employed by the Company or its subsidiaries.

7. Legend. Any certificates representing unvested Shares shall bear a legend substantially in the following form:

THE TRANSFERABILITY OF THIS CERTIFICATE AND THE SHARES OF STOCK REPRESENTED HEREBY ARE SUBJECT TO THE TERMS AND CONDITIONS (INCLUDING FORFEITURE) OF AN INCENTIVE PLAN AND A RESTRICTED STOCK AWARD AGREEMENT ENTERED INTO BETWEEN THE REGISTERED OWNER AND CONTROL DELIVERY SYSTEMS, INC. COPIES OF SUCH PLAN AND AGREEMENT ARE ON FILE IN THE OFFICES OF CONTROL DELIVERY SYSTEMS, INC.

As soon as practicable following the vesting of any such Shares, the Company shall cause a certificate or certificates covering such Shares to be issued and delivered to Employee, containing a legend substantially in the following form:

THE SHARES OF STOCK REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS UPON TRANSFER SET FORTH IN A RESTRICTED STOCK AWARD AGREEMENT. THE CORPORATION WILL FURNISH A COPY OF SUCH AGREEMENT TO THE HOLDER OF THIS CERTIFICATE UPON WRITTEN REQUEST AND WITHOUT CHARGE.

If any Shares are held in book-entry form, the Company may take such steps as it deems necessary or appropriate to record and manifest the restrictions applicable to such Shares.

8. Dividends, etc. Employee shall be entitled to (i) receive regular cash dividends, if any, paid with respect to those Shares of which Employee is the record owner on the record date for

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such dividend, and (ii) vote any Shares of which Employee is the record owner on the record date for such vote. Any dividends and distributions (other than any regular cash dividends) distributed with respect to any Shares or any securities of the Company or any other entity into which the Shares are converted or for which they are exchanged (the "associated share"), including without limitation a distribution of stock by reason of a stock dividend, stock split or otherwise with respect to an associated share, or a distribution of other securities with respect to an associated share, shall be subject to the restrictions of this Agreement in the same manner and for so long as the associated share remains subject to such restrictions, and shall be forfeited if and when the associated share is so forfeited. The administrator of the Plan may require that any cash distribution with respect to the Shares other than a regular cash dividend be placed in escrow or otherwise made subject to such restrictions as the administrator of the Plan deems appropriate. References in this Agreement to the Shares shall refer, with the necessary changes having been made, to any such restricted amounts.

9. Restriction on Transfer of Vested Shares.

a. Employee shall not sell, assign, transfer, pledge, hypothecate, give or otherwise dispose of, by operation of law or otherwise (collectively "transfer"), any of the Shares once they have vested ("Vested Shares"), or any interest therein, unless such transfer shall be made in compliance with the provisions of this Section 9 and the provisions of Sections 10 and 11 of this Agreement.

b. Notwithstanding Section 10 hereof, Employee shall not transfer any Vested Shares unless either (i) a registration statement under the Securities Act of 1933, as amended (the "Act"), with respect to the Vested Shares shall have become, and continues to be, effective, or (ii) the Company receives an opinion of counsel reasonably satisfactory to it that registration of such Vested Shares is not required under the Act.

10. Right of First Refusal on Dispositions of Vested Shares.

a. Receipt of Third-Party Offer. If at any time Employee desires to sell for cash, cash equivalents or any other form of consideration (including a promissory note) Vested Shares pursuant to an offer or proposed offer from a third party (the "Proposed Transferee"), Employee shall submit a written offer (the "Offer") to sell such Vested Shares (the "Offered Shares") to the Company on terms and conditions, including price, not less favorable to the Company than those on which Employee proposes to sell such Offered Shares to the Proposed Transferee. The Offer shall disclose the identity of the Proposed Transferee, the number of Offered Shares proposed to be sold, the total number of Vested Shares owned by Employee, the terms and conditions, including price, of the proposed sale, and any other material facts relating to the proposed sale. The Offer shall further state that the Company may acquire, in accordance with the provisions of this Agreement, all or any portion of the Offered Shares for the price and upon the other terms and conditions, including deferred payment (if applicable), set forth therein.

b. Company Notice of Intent to Purchase. If the Company desires to purchase all or any portion of the Offered Shares, the Company shall give to Employee written notice of the number of Offered Shares to be purchased by it within 30 days of the date of the Offer. Such communication shall, when taken in conjunction with the Offer, be deemed to constitute a valid,

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legally binding and enforceable agreement for the sale and purchase of the Offered Shares. Sale of the Offered Shares to the Company pursuant to this Section 10 shall be made at the offices of the Company on the 45th day following the date of the Offer (or, if such day is not a business day, then on the next succeeding business day). Such sale shall be effected by Employee's delivery to the Company of a certificate or certificates evidencing the Offered Shares to be purchased by the Company, duly endorsed for transfer to the Company, against payment to Employee of the purchase price therefor by the Company by a certified or cashier's check.

c. Sale to Third Party. If, within 30 days of its receipt of notice of the Offer, the Company fails to deliver written notice to Employee of its intention to purchase all of the Offered Shares (the Offered Shares which the Company does not elect to purchase being referred to as the "Refused Shares"), the Refused Shares not so purchased may be sold by Employee at any time within 90 days after the date of the Offer, at not less than the price and upon other terms and conditions, if any, not more favorable to the Proposed Transferee than those specified in the Offer. If the Refused Shares are not sold within such 90 day period, they shall continue to be subject to the requirements of a prior offer pursuant to this Section 10. If the Refused Shares are sold pursuant to this section 10 to any purchaser who is not a party to an agreement with the Company containing restrictions on the transfer of the Vested Shares to the same extent as those contained herein, the Company, may at its option, require the purchaser of Vested Shares the same as those set forth in this Agreement.

d. Permitted Transfers. Employee shall have the right to make Permitted Transfers (as defined below) of Employee's Vested Shares and the provisions of subsections (a), (b) and (c) above shall not apply to any such Permitted Transfer by Employee. For purposes of this Agreement, "Permitted Transfer" shall mean any transfer by Employee during his or her lifetime of all or any portion of the Vested Shares (i) to the Company; or (ii) to any parent, spouse, child, grandchild, brother, sister or the spouse of a child, grandchild, brother or sister (a "Member of the Immediate Family") of Employee, to a trust created for the benefit of a Member of the Immediate Family of Employee or to a custodian of a property of one or more such persons, or to a limited partnership or limited liability company all partners or members of which are Members of the Immediate Family of Employee, any of such transfers to include transfers by will or the laws of descent and distribution; provided, however, that, it shall be a condition of each such transfer, that (x) the transferee agrees to be bound by the terms of this Agreement, including without limitation Sections 10, 11 and 13, as though no such transfer had taken place, and that (y) Employee has complied with all applicable laws in connection with such transfer.

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### 11. Right of Repurchase of Vested Shares.

a. Termination of Employment Relationship. If Employee's employment or other service relationship with the Company terminates, voluntarily or involuntarily, for any reason, the Company shall have the right to purchase, and Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement) shall, at the election of the Company, be obligated to sell, all or any part of Employee's Vested Shares at the purchase price and on the terms provided in this Section 11 (the "Repurchase Right").

b. Exercise of Repurchase Right. The Company may exercise the Repurchase Right by giving to Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement), within 30 days of the date on which Employee's employment or other service relationship with the Company terminates (the "Termination Date"), written notice of (i) the number of Vested Shares to be purchased by it, and (ii) the purchase price, as determined in a manner provided below, to be paid for such Vested Shares. Such communication shall be deemed to constitute a valid, legally binding and enforceable agreement for the sale and purchase of the Vested Shares.

The purchase price of Vested Shares purchased by the Company pursuant to this Section 11 shall be the fair market value of such Vested Shares on the Termination Date, as conclusively determined by the Board of Directors of the Company after taking into consideration such factors as it deems appropriate.

Sale of the Vested Shares to the Company pursuant to this Section 11 shall be made at the offices of the Company on the 45th day following the Termination Date (or, if such day is not a business day, then on the next succeeding business day) or such earlier business day of which the Company shall notify Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement). Such sale shall be effected by the delivery to the Company of a certificate or certificates evidencing the Vested Shares to be purchased by the Company, duly endorsed for transfer to the Company, against payment to Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement) of the purchase price therefor by the Company by a certified or cashier's check.

12. Effect of Prohibited Transfer. The Company shall not be required (a) to transfer on its books any Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Agreement, or (b) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

13. Initial Public Offering. Upon the closing of the first underwritten public offering by the Company under the Act of its Stock for its own account for cash: (a) Sections 9(a), 10 and 11 of this Agreement shall terminate except as to Offers accepted and Repurchase Rights exercised by the Company prior to such date; (b) without the prior written approval of the Company, Employee agrees not to, directly or indirectly, make or cause any offering, sale, short sale, hypothecation, pledge or other disposition of any Vested Shares until the date 180 days after the effective date of the registration statement filed with the Securities and Exchange Commission pursuant to the Act by the Company in connection with such offering (the "Holdback Period"); and (c) Employee shall, if so requested by the Company, sign an agreement with the

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underwriters of the offering containing such terms and provisions requested by such underwriters substantially similar to those contained in this Section 13. The Company may impose stop-transfer instructions with respect to the Shares or other securities subject to the foregoing restrictions until the end of the Holdback Period.

14. Termination of Restrictions on Transfer. The restrictions on the transfer of Vested Shares contained in Sections 11 through 13 of this Agreement, and the obligations of Employee and the Company set forth therein, except as to Offers accepted and Repurchase Rights exercised by the Company prior to a Change in Control, shall terminate upon a Change in Control, as defined below. The transfer of the Shares pursuant to a Change in Control shall not be subject to the provisions of Sections 9(a) and 10 of this Agreement.

For purposes of this Section 14, Change in Control shall mean:

(i) the acquisition by any Person or group of the ultimate beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of more than 50% of the then outstanding securities of the Company entitled to vote generally in the election of directors; excluding, however, the following: (A) any acquisition directly from the Company (excluding any acquisition by virtue of the exercise of an exercise, conversion or exchange privilege unless the security being so exercised, converted or exchanged was itself acquired directly from the Company), (B) any acquisition by the Company, or (C) any acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company or by any corporation controlled by the Company; or

(ii) a reorganization, recapitalization, merger or consolidation (a "Corporate Transaction") of the Company, unless securities representing more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the Company or such corporation after such Corporate Transaction) are beneficially owned subsequent to such Corporate Transaction by the Person or Persons who were the beneficial owners of the outstanding securities of the Company entitled to vote generally in the election of directors immediately prior to such Corporate Transaction, in substantially the same proportions as their ownership immediately prior to such Corporate Transaction; or

(iii) the sale, transfer or other disposition of all or substantially all of the assets of the Company; or

(iv) the dissolution or liquidation of the Company.

For purposes of this definition, securities entitled to vote generally in the election of directors that are issuable upon exercise of an exercise, conversion or exchange privilege shall be deemed to be outstanding. In addition, for purposes of this definition the following terms have the meanings set forth below:

A Person will be deemed to be the "owner" of any securities of which such Person would be the "beneficial owner," as such term is defined in Rule 13d-3 promulgated by the Securities and Exchange Commission under the Exchange Act.

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"Person" has the meaning used in Section 13(d) of the Exchange Act, except that "Person" does not include the Company or a wholly owned subsidiary of the Company or an employee benefit plan (or related trust) of the Company or of a wholly owned subsidiary.

15. Certain Tax Matters. Employee expressly acknowledges the following:

a. Employee has been advised to confer promptly with a professional tax advisor to consider whether Employee should make a so-called "83(b) election" with respect to the Shares. Any such election, to be effective, must be made in accordance with applicable regulations and within thirty (30) days following the date of this Award. The Company has made no recommendation to Employee with respect to the advisability of making such an election.

b. The award or vesting of the Shares acquired hereunder, and the payment of dividends with respect to such Shares, may give rise to "wages" subject to withholding. Employee expressly acknowledges and agrees that Employee's rights hereunder are subject to Employee's promptly paying to the Company in cash (or by such other means as may be acceptable to the Company in its discretion, including, if the administrator of the Plan so determines, by the delivery of previously acquired Stock or shares of Stock acquired hereunder or by the withholding of amounts from any payment hereunder) all taxes required to be withheld in connection with such award, vesting or payment.

16. No Employment Rights. Nothing in the Plan, the Award or this Agreement confers upon the Employee any right to continued employment or interferes with the right of the Company to terminate Employee's employment at any time.

17. Severability; Governing Law. If any provisions of this Agreement shall be determined to be illegal or unenforceable by any court of law, the remaining provisions shall be severable and enforceable in accordance with their terms. This Agreement shall be governed by, and construed in accordance with, the laws of Delaware, excluding its choice of law provisions.

18. Injunctive Relief. It is acknowledged that it will be impossible to measure the damages that would be suffered by the Company if Employee fails to comply with the provisions of this Agreement and that, in the event of any such failure, the Company will not have an adequate remedy at law. The Company shall, therefore, be entitled to obtain specific performance of each of Employee's obligations hereunder and to obtain immediate injunctive relief without the requirement of posting a bond. Employee shall not urge, as a defense to any proceeding for such specific performance or injunctive relief, that the Company has an adequate remedy at law.

19. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors and permitted assigns.

20. Amendments. Except as provided below, the Board may at any time or times amend the Plan or this Agreement for the purpose of satisfying the requirements of any changes in applicable laws or regulations or for any other purpose which at the time may be permitted by law. Sections 9 through 11 of this Agreement, containing restrictions on the transfer of Shares, may be amended or modified only by a written instrument executed by both the Company and Employee. No termination or amendment of the Plan or amendment of this Agreement shall,

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without Employee's consent, adversely affect Employee's rights under the Plan or this Agreement.

21. Notices. All notices required or permitted hereunder shall be in writing and deemed effectively given upon personal delivery, upon deposit with the United States Post Office, by registered or certified mail, postage prepaid, or upon deposit with a recognized express overnight courier service, addressed, if to the Company, to 400 Pleasant Street, Watertown, MA 02472, attention: Chief Financial Officer, and if to Employee, to the address shown beneath his or her respective signature to this Agreement, or at such other address or addresses as either party shall designate to the other in accordance with this Section 21.

22. Merger Provision. This Agreement, including the Plan which is incorporated herein by reference in its entirety, constitutes the entire agreement between the parties hereto pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements and understandings, whether oral or written, of the parties hereto concerning the subject matter hereof.

23. Waivers. Any provision contained in this Agreement may be waived, either generally or in any particular instance, by the Company.

24. Definition. As used in this Agreement, the term "Company" shall include any subsidiary or parent of the Company as defined in Sections 424(e) and (f) of the Code.

25. Consistency with Plan. If there is any inconsistency between the provisions of this Agreement and the provisions of the Plan, the Plan shall control.

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Name of Employee: Paul Ashton

Number of Shares of Restricted Stock granted: 20,000

Date of Grant: August 16, 2004

The foregoing Restricted Stock Award is hereby accepted and in consideration of the grant of such Award, the undersigned Employee hereby agrees with Control Delivery Systems, Inc. that the undersigned will be bound by the foregoing Restricted Stock Award Agreement:

/s/ Paul Ashton

- ----- (Signature of Employee)

Dated: \_\_\_\_\_, 2004

# CONTROL DELIVERY SYSTEMS, INC. 2001 INCENTIVE PLAN

#### Restricted Stock Award Agreement

The undersigned employee ("Employee") has been granted an award (the "Award") of restricted stock from Control Delivery Systems, Inc. (the "Company") under the 2001 Incentive Plan (the "Plan"), subject to the terms set forth below and in the Plan, a copy of which as currently in effect has been delivered to Employee. In consideration of the grant of the Award, the Employee agrees with the Company as follows:

1. Effective Date. This Agreement shall take effect as of the date of grant of the Award, as indicated on the signature page hereof.

2. Shares Subject to Award. The Award consists of the number of shares set forth on the signature page hereof (the "Shares") of common stock of the Company ("Stock"). Employee's rights to the Shares are subject to the restrictions described in this Agreement and the Plan in addition to such other restrictions, if any, as may be imposed by law.

3. Meaning of Certain Terms. Except as otherwise expressly provided, all terms used herein shall have the same meaning as in the Plan. The term "vest" as used herein with respect to any Share means the lapsing of the restrictions described herein with respect to such Share.

4. Nontransferability of Shares. The Shares cannot be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until they have vested, and then only as provided below and in the Plan.

5. Forfeiture Risk. If Employee ceases to be employed by the Company and its subsidiaries for any reason, including death, any then outstanding and unvested Shares shall be automatically and immediately forfeited. Employee hereby (i) appoints the Company as the attorney-in-fact of Employee to take such actions as may be necessary or appropriate to effectuate a transfer of the record ownership of any such shares that are unvested and forfeited hereunder, (ii) agrees to deliver to the Company, as a precondition to the issuance of any certificate or certificates with respect to unvested Shares hereunder, one or more stock powers, endorsed in blank, with respect to such Shares, and (iii) agrees to sign such other powers and take such other actions as the Company may reasonably request to accomplish the transfer or forfeiture of any unvested Shares that are forfeited hereunder.

6. Vesting of Shares. The Shares shall vest in accordance with the provisions of this Paragraph 6 and applicable provisions of the Plan (if not earlier in accordance with the Plan, including Section 6 of the Plan), as follows:

100% of the Shares will vest on the earlier to occur of:

- October 7, 2005; or
- a Liquidity Event Date (as defined below).

PAGE 1 OF 9

Notwithstanding the foregoing, in the event that a Liquidity Event Date that relates to an initial public offering occurs on or before October 7, 2005, 100% of the Shares shall vest on that date which is the six-month anniversary of the closing of the initial public offering.

Any securities of the Company or any other entity, and any cash and other consideration, into which the Shares are converted or for which they are exchanged, by reason of a merger, consolidation, sale of assets, reorganization or other transaction, shall vest (by their terms or through the use of an escrow, a commitment to deliver in the future or such other device as is determined by the administrator of the Plan) on the same terms as the Shares from which they were converted or for which they were exchanged.

A "Liquidity Event" means any public offering, merger, consolidation, sale of assets, reorganization or other transaction in or as a result of which the Stock of the Company (or the stock or other securities into or for which such Stock is converted or exchanged) are or become registered under the Securities Exchange Act of 1934 or are converted into or exchanged for cash. "Liquidity Event Date" shall mean the date of the closing of a Liquidity Event.

Notwithstanding the foregoing, no Shares shall vest on any vesting date specified above unless Employee is then, and since the date of grant has continuously been, employed by the Company or its subsidiaries.

7. Legend. Any certificates representing unvested Shares shall bear a legend substantially in the following form:

THE TRANSFERABILITY OF THIS CERTIFICATE AND THE SHARES OF STOCK REPRESENTED HEREBY ARE SUBJECT TO THE TERMS AND CONDITIONS (INCLUDING FORFEITURE) OF AN INCENTIVE PLAN AND A RESTRICTED STOCK AWARD AGREEMENT ENTERED INTO BETWEEN THE REGISTERED OWNER AND CONTROL DELIVERY SYSTEMS, INC. COPIES OF SUCH PLAN AND AGREEMENT ARE ON FILE IN THE OFFICES OF CONTROL DELIVERY SYSTEMS, INC.

As soon as practicable following the vesting of any such Shares, the Company shall cause a certificate or certificates covering such Shares to be issued and delivered to Employee, containing a legend substantially in the following form:

THE SHARES OF STOCK REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS UPON TRANSFER SET FORTH IN A RESTRICTED STOCK AWARD AGREEMENT. THE CORPORATION WILL FURNISH A COPY OF SUCH AGREEMENT TO THE HOLDER OF THIS CERTIFICATE UPON WRITTEN REQUEST AND WITHOUT CHARGE.

If any Shares are held in book-entry form, the Company may take such steps as it deems necessary or appropriate to record and manifest the restrictions applicable to such Shares.

8. Dividends, etc. Employee shall be entitled to (i) receive regular cash dividends, if any, paid with respect to those Shares of which Employee is the record owner on the record date for

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such dividend, and (ii) vote any Shares of which Employee is the record owner on the record date for such vote. Any dividends and distributions (other than any regular cash dividends) distributed with respect to any Shares or any securities of the Company or any other entity into which the Shares are converted or for which they are exchanged (the "associated share"), including without limitation a distribution of stock by reason of a stock dividend, stock split or otherwise with respect to an associated share, or a distribution of other securities with respect to an associated share, shall be subject to the restrictions of this Agreement in the same manner and for so long as the associated share remains subject to such restrictions, and shall be forfeited if and when the associated share is so forfeited. The administrator of the Plan may require that any cash distribution with respect to the Shares other than a regular cash dividend be placed in escrow or otherwise made subject to such restrictions as the administrator of the Plan deems appropriate. References in this Agreement to the Shares shall refer, with the necessary changes having been made, to any such restricted amounts.

9. Restriction on Transfer of Vested Shares.

a. Employee shall not sell, assign, transfer, pledge, hypothecate, give or otherwise dispose of, by operation of law or otherwise (collectively "transfer"), any of the Shares once they have vested ("Vested Shares"), or any interest therein, unless such transfer shall be made in compliance with the provisions of this Section 9 and the provisions of Sections 10 and 11 of this Agreement.

b. Notwithstanding Section 10 hereof, Employee shall not transfer any Vested Shares unless either (i) a registration statement under the Securities Act of 1933, as amended (the "Act"), with respect to the Vested Shares shall have become, and continues to be, effective, or (ii) the Company receives an opinion of counsel reasonably satisfactory to it that registration of such Vested Shares is not required under the Act.

10. Right of First Refusal on Dispositions of Vested Shares.

a. Receipt of Third-Party Offer. If at any time Employee desires to sell for cash, cash equivalents or any other form of consideration (including a promissory note) Vested Shares pursuant to an offer or proposed offer from a third party (the "Proposed Transferee"), Employee shall submit a written offer (the "Offer") to sell such Vested Shares (the "Offered Shares") to the Company on terms and conditions, including price, not less favorable to the Company than those on which Employee proposes to sell such Offered Shares to the Proposed Transferee. The Offer shall disclose the identity of the Proposed Transferee, the number of Offered Shares proposed to be sold, the total number of Vested Shares owned by Employee, the terms and conditions, including price, of the proposed sale, and any other material facts relating to the proposed sale. The Offer shall further state that the Company may acquire, in accordance with the provisions of this Agreement, all or any portion of the Offered Shares for the price and upon the other terms and conditions, including deferred payment (if applicable), set forth therein.

b. Company Notice of Intent to Purchase. If the Company desires to purchase all or any portion of the Offered Shares, the Company shall give to Employee written notice of the number of Offered Shares to be purchased by it within 30 days of the date of the Offer. Such communication shall, when taken in conjunction with the Offer, be deemed to constitute a valid,

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legally binding and enforceable agreement for the sale and purchase of the Offered Shares. Sale of the Offered Shares to the Company pursuant to this Section 10 shall be made at the offices of the Company on the 45th day following the date of the Offer (or, if such day is not a business day, then on the next succeeding business day). Such sale shall be effected by Employee's delivery to the Company of a certificate or certificates evidencing the Offered Shares to be purchased by the Company, duly endorsed for transfer to the Company, against payment to Employee of the purchase price therefor by the Company by a certified or cashier's check.

c. Sale to Third Party. If, within 30 days of its receipt of notice of the Offer, the Company fails to deliver written notice to Employee of its intention to purchase all of the Offered Shares (the Offered Shares which the Company does not elect to purchase being referred to as the "Refused Shares"), the Refused Shares not so purchased may be sold by Employee at any time within 90 days after the date of the Offer, at not less than the price and upon other terms and conditions, if any, not more favorable to the Proposed Transferee than those specified in the Offer. If the Refused Shares are not sold within such 90 day period, they shall continue to be subject to the requirements of a prior offer pursuant to this Section 10. If the Refused Shares are sold pursuant to this section 10 to any purchaser who is not a party to an agreement with the Company containing restrictions on the transfer of the Vested Shares to the same extent as those contained herein, the Company, may at its option, require the purchaser of Vested Shares the same as those set forth in this Agreement.

d. Permitted Transfers. Employee shall have the right to make Permitted Transfers (as defined below) of Employee's Vested Shares and the provisions of subsections (a), (b) and (c) above shall not apply to any such Permitted Transfer by Employee. For purposes of this Agreement, "Permitted Transfer" shall mean any transfer by Employee during his or her lifetime of all or any portion of the Vested Shares (i) to the Company; or (ii) to any parent, spouse, child, grandchild, brother, sister or the spouse of a child, grandchild, brother or sister (a "Member of the Immediate Family") of Employee, to a trust created for the benefit of a Member of the Immediate Family of Employee or to a custodian of a property of one or more such persons, or to a limited partnership or limited liability company all partners or members of which are Members of the Immediate Family of Employee, any of such transfers to include transfers by will or the laws of descent and distribution; provided, however, that, it shall be a condition of each such transfer, that (x) the transferee agrees to be bound by the terms of this Agreement, including without limitation Sections 10, 11 and 13, as though no such transfer had taken place, and that (y) Employee has complied with all applicable laws in connection with such transfer.

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### 11. Right of Repurchase of Vested Shares.

a. Termination of Employment Relationship. If Employee's employment or other service relationship with the Company terminates, voluntarily or involuntarily, for any reason, the Company shall have the right to purchase, and Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement) shall, at the election of the Company, be obligated to sell, all or any part of Employee's Vested Shares at the purchase price and on the terms provided in this Section 11 (the "Repurchase Right").

b. Exercise of Repurchase Right. The Company may exercise the Repurchase Right by giving to Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement), within 30 days of the date on which Employee's employment or other service relationship with the Company terminates (the "Termination Date"), written notice of (i) the number of Vested Shares to be purchased by it, and (ii) the purchase price, as determined in a manner provided below, to be paid for such Vested Shares. Such communication shall be deemed to constitute a valid, legally binding and enforceable agreement for the sale and purchase of the Vested Shares.

The purchase price of Vested Shares purchased by the Company pursuant to this Section 11 shall be the fair market value of such Vested Shares on the Termination Date, as conclusively determined by the Board of Directors of the Company after taking into consideration such factors as it deems appropriate.

Sale of the Vested Shares to the Company pursuant to this Section 11 shall be made at the offices of the Company on the 45th day following the Termination Date (or, if such day is not a business day, then on the next succeeding business day) or such earlier business day of which the Company shall notify Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement). Such sale shall be effected by the delivery to the Company of a certificate or certificates evidencing the Vested Shares to be purchased by the Company, duly endorsed for transfer to the Company, against payment to Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement) of the purchase price therefor by the Company by a certified or cashier's check.

12. Effect of Prohibited Transfer. The Company shall not be required (a) to transfer on its books any Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Agreement, or (b) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

13. Initial Public Offering. Upon the closing of the first underwritten public offering by the Company under the Act of its Stock for its own account for cash: (a) Sections 9(a), 10 and 11 of this Agreement shall terminate except as to Offers accepted and Repurchase Rights exercised by the Company prior to such date; (b) without the prior written approval of the Company, Employee agrees not to, directly or indirectly, make or cause any offering, sale, short sale, hypothecation, pledge or other disposition of any Vested Shares until the date 180 days after the effective date of the registration statement filed with the Securities and Exchange Commission pursuant to the Act by the Company in connection with such offering (the "Holdback Period"); and (c) Employee shall, if so requested by the Company, sign an agreement with the

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underwriters of the offering containing such terms and provisions requested by such underwriters substantially similar to those contained in this Section 13. The Company may impose stop-transfer instructions with respect to the Shares or other securities subject to the foregoing restrictions until the end of the Holdback Period.

14. Termination of Restrictions on Transfer. The restrictions on the transfer of Vested Shares contained in Sections 11 through 13 of this Agreement, and the obligations of Employee and the Company set forth therein, except as to Offers accepted and Repurchase Rights exercised by the Company prior to a Change in Control, shall terminate upon a Change in Control, as defined below. The transfer of the Shares pursuant to a Change in Control shall not be subject to the provisions of Sections 9(a) and 10 of this Agreement.

For purposes of this Section 14, Change in Control shall mean:

(i) the acquisition by any Person or group of the ultimate beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of more than 50% of the then outstanding securities of the Company entitled to vote generally in the election of directors; excluding, however, the following: (A) any acquisition directly from the Company (excluding any acquisition by virtue of the exercise of an exercise, conversion or exchange privilege unless the security being so exercised, converted or exchanged was itself acquired directly from the Company), (B) any acquisition by the Company, or (C) any acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company or by any corporation controlled by the Company; or

(ii) a reorganization, recapitalization, merger or consolidation (a "Corporate Transaction") of the Company, unless securities representing more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the Company or such corporation after such Corporate Transaction) are beneficially owned subsequent to such Corporate Transaction by the Person or Persons who were the beneficial owners of the outstanding securities of the Company entitled to vote generally in the election of directors immediately prior to such Corporate Transaction, in substantially the same proportions as their ownership immediately prior to such Corporate Transaction; or

(iii) the sale, transfer or other disposition of all or substantially all of the assets of the Company; or

(iv) the dissolution or liquidation of the Company.

For purposes of this definition, securities entitled to vote generally in the election of directors that are issuable upon exercise of an exercise, conversion or exchange privilege shall be deemed to be outstanding. In addition, for purposes of this definition the following terms have the meanings set forth below:

A Person will be deemed to be the "owner" of any securities of which such Person would be the "beneficial owner," as such term is defined in Rule 13d-3 promulgated by the Securities and Exchange Commission under the Exchange Act.

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"Person" has the meaning used in Section 13(d) of the Exchange Act, except that "Person" does not include the Company or a wholly owned subsidiary of the Company or an employee benefit plan (or related trust) of the Company or of a wholly owned subsidiary.

15. Certain Tax Matters. Employee expressly acknowledges the following:

a. Employee has been advised to confer promptly with a professional tax advisor to consider whether Employee should make a so-called "83(b) election" with respect to the Shares. Any such election, to be effective, must be made in accordance with applicable regulations and within thirty (30) days following the date of this Award. The Company has made no recommendation to Employee with respect to the advisability of making such an election.

b. The award or vesting of the Shares acquired hereunder, and the payment of dividends with respect to such Shares, may give rise to "wages" subject to withholding. Employee expressly acknowledges and agrees that Employee's rights hereunder are subject to Employee's promptly paying to the Company in cash (or by such other means as may be acceptable to the Company in its discretion, including, if the administrator of the Plan so determines, by the delivery of previously acquired Stock or shares of Stock acquired hereunder or by the withholding of amounts from any payment hereunder) all taxes required to be withheld in connection with such award, vesting or payment.

16. No Employment Rights. Nothing in the Plan, the Award or this Agreement confers upon the Employee any right to continued employment or interferes with the right of the Company to terminate Employee's employment at any time.

17. Severability; Governing Law. If any provisions of this Agreement shall be determined to be illegal or unenforceable by any court of law, the remaining provisions shall be severable and enforceable in accordance with their terms. This Agreement shall be governed by, and construed in accordance with, the laws of Delaware, excluding its choice of law provisions.

18. Injunctive Relief. It is acknowledged that it will be impossible to measure the damages that would be suffered by the Company if Employee fails to comply with the provisions of this Agreement and that, in the event of any such failure, the Company will not have an adequate remedy at law. The Company shall, therefore, be entitled to obtain specific performance of each of Employee's obligations hereunder and to obtain immediate injunctive relief without the requirement of posting a bond. Employee shall not urge, as a defense to any proceeding for such specific performance or injunctive relief, that the Company has an adequate remedy at law.

19. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors and permitted assigns.

20. Amendments. Except as provided below, the Board may at any time or times amend the Plan or this Agreement for the purpose of satisfying the requirements of any changes in applicable laws or regulations or for any other purpose which at the time may be permitted by law. Sections 9 through 11 of this Agreement, containing restrictions on the transfer of Shares, may be amended or modified only by a written instrument executed by both the Company and Employee. No termination or amendment of the Plan or amendment of this Agreement shall,

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without Employee's consent, adversely affect Employee's rights under the Plan or this Agreement.

21. Notices. All notices required or permitted hereunder shall be in writing and deemed effectively given upon personal delivery, upon deposit with the United States Post Office, by registered or certified mail, postage prepaid, or upon deposit with a recognized express overnight courier service, addressed, if to the Company, to 400 Pleasant Street, Watertown, MA 02472, attention: Chief Financial Officer, and if to Employee, to the address shown beneath his or her respective signature to this Agreement, or at such other address or addresses as either party shall designate to the other in accordance with this Section 21.

22. Merger Provision. This Agreement, including the Plan which is incorporated herein by reference in its entirety, constitutes the entire agreement between the parties hereto pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements and understandings, whether oral or written, of the parties hereto concerning the subject matter hereof.

23. Waivers. Any provision contained in this Agreement may be waived, either generally or in any particular instance, by the Company.

24. Definition. As used in this Agreement, the term "Company" shall include any subsidiary or parent of the Company as defined in Sections 424(e) and (f) of the Code.

25. Consistency with Plan. If there is any inconsistency between the provisions of this Agreement and the provisions of the Plan, the Plan shall control.

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Name of Employee: Michael J. Soja

Number of Shares of Restricted Stock granted: 20,000

Date of Grant: August 16, 2004

The foregoing Restricted Stock Award is hereby accepted and in consideration of the grant of such Award, the undersigned Employee hereby agrees with Control Delivery Systems, Inc. that the undersigned will be bound by the foregoing Restricted Stock Award Agreement:

/s/ Michael J. Soja

(Signature of Employee)

Dated: \_\_\_\_\_, 2004

# CONTROL DELIVERY SYSTEMS, INC. 2001 INCENTIVE PLAN

#### Restricted Stock Award Agreement

The undersigned employee ("Employee") has been granted an award (the "Award") of restricted stock from Control Delivery Systems, Inc. (the "Company") under the 2001 Incentive Plan (the "Plan"), subject to the terms set forth below and in the Plan, a copy of which as currently in effect has been delivered to Employee. In consideration of the grant of the Award, the Employee agrees with the Company as follows:

1. Effective Date. This Agreement shall take effect as of the date of grant of the Award, as indicated on the signature page hereof.

2. Shares Subject to Award. The Award consists of the number of shares set forth on the signature page hereof (the "Shares") of common stock of the Company ("Stock"). Employee's rights to the Shares are subject to the restrictions described in this Agreement and the Plan in addition to such other restrictions, if any, as may be imposed by law.

3. Meaning of Certain Terms. Except as otherwise expressly provided, all terms used herein shall have the same meaning as in the Plan. The term "vest" as used herein with respect to any Share means the lapsing of the restrictions described herein with respect to such Share.

4. Nontransferability of Shares. The Shares cannot be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until they have vested, and then only as provided below and in the Plan.

5. Forfeiture Risk. If Employee ceases to be employed by the Company and its subsidiaries for any reason, including death, any then outstanding and unvested Shares shall be automatically and immediately forfeited. Employee hereby (i) appoints the Company as the attorney-in-fact of Employee to take such actions as may be necessary or appropriate to effectuate a transfer of the record ownership of any such shares that are unvested and forfeited hereunder, (ii) agrees to deliver to the Company, as a precondition to the issuance of any certificate or certificates with respect to unvested Shares hereunder, one or more stock powers, endorsed in blank, with respect to such Shares, and (iii) agrees to sign such other powers and take such other actions as the Company may reasonably request to accomplish the transfer or forfeiture of any unvested Shares that are forfeited hereunder.

6. Vesting of Shares. The Shares shall vest in accordance with the provisions of this Paragraph 6 and applicable provisions of the Plan (if not earlier in accordance with the Plan, including Section 6 of the Plan), as follows:

100% of the Shares will vest on the earlier to occur of:

- October 7, 2005; or
- a Liquidity Event Date (as defined below).

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Notwithstanding the foregoing, in the event that a Liquidity Event Date that relates to an initial public offering occurs on or before October 7, 2005, 100% of the Shares shall vest on that date which is the six-month anniversary of the closing of the initial public offering.

Any securities of the Company or any other entity, and any cash and other consideration, into which the Shares are converted or for which they are exchanged, by reason of a merger, consolidation, sale of assets, reorganization or other transaction, shall vest (by their terms or through the use of an escrow, a commitment to deliver in the future or such other device as is determined by the administrator of the Plan) on the same terms as the Shares from which they were converted or for which they were exchanged.

A "Liquidity Event" means any public offering, merger, consolidation, sale of assets, reorganization or other transaction in or as a result of which the Stock of the Company (or the stock or other securities into or for which such Stock is converted or exchanged) are or become registered under the Securities Exchange Act of 1934 or are converted into or exchanged for cash. "Liquidity Event Date" shall mean the date of the closing of a Liquidity Event.

Notwithstanding the foregoing, no Shares shall vest on any vesting date specified above unless Employee is then, and since the date of grant has continuously been, employed by the Company or its subsidiaries.

7. Legend. Any certificates representing unvested Shares shall bear a legend substantially in the following form:

THE TRANSFERABILITY OF THIS CERTIFICATE AND THE SHARES OF STOCK REPRESENTED HEREBY ARE SUBJECT TO THE TERMS AND CONDITIONS (INCLUDING FORFEITURE) OF AN INCENTIVE PLAN AND A RESTRICTED STOCK AWARD AGREEMENT ENTERED INTO BETWEEN THE REGISTERED OWNER AND CONTROL DELIVERY SYSTEMS, INC. COPIES OF SUCH PLAN AND AGREEMENT ARE ON FILE IN THE OFFICES OF CONTROL DELIVERY SYSTEMS, INC.

As soon as practicable following the vesting of any such Shares, the Company shall cause a certificate or certificates covering such Shares to be issued and delivered to Employee, containing a legend substantially in the following form:

THE SHARES OF STOCK REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS UPON TRANSFER SET FORTH IN A RESTRICTED STOCK AWARD AGREEMENT. THE CORPORATION WILL FURNISH A COPY OF SUCH AGREEMENT TO THE HOLDER OF THIS CERTIFICATE UPON WRITTEN REQUEST AND WITHOUT CHARGE.

If any Shares are held in book-entry form, the Company may take such steps as it deems necessary or appropriate to record and manifest the restrictions applicable to such Shares.

8. Dividends, etc. Employee shall be entitled to (i) receive regular cash dividends, if any, paid with respect to those Shares of which Employee is the record owner on the record date for

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such dividend, and (ii) vote any Shares of which Employee is the record owner on the record date for such vote. Any dividends and distributions (other than any regular cash dividends) distributed with respect to any Shares or any securities of the Company or any other entity into which the Shares are converted or for which they are exchanged (the "associated share"), including without limitation a distribution of stock by reason of a stock dividend, stock split or otherwise with respect to an associated share, or a distribution of other securities with respect to an associated share, shall be subject to the restrictions of this Agreement in the same manner and for so long as the associated share remains subject to such restrictions, and shall be forfeited if and when the associated share is so forfeited. The administrator of the Plan may require that any cash distribution with respect to the Shares other than a regular cash dividend be placed in escrow or otherwise made subject to such restrictions as the administrator of the Plan deems appropriate. References in this Agreement to the Shares shall refer, with the necessary changes having been made, to any such restricted amounts.

9. Restriction on Transfer of Vested Shares.

a. Employee shall not sell, assign, transfer, pledge, hypothecate, give or otherwise dispose of, by operation of law or otherwise (collectively "transfer"), any of the Shares once they have vested ("Vested Shares"), or any interest therein, unless such transfer shall be made in compliance with the provisions of this Section 9 and the provisions of Sections 10 and 11 of this Agreement.

b. Notwithstanding Section 10 hereof, Employee shall not transfer any Vested Shares unless either (i) a registration statement under the Securities Act of 1933, as amended (the "Act"), with respect to the Vested Shares shall have become, and continues to be, effective, or (ii) the Company receives an opinion of counsel reasonably satisfactory to it that registration of such Vested Shares is not required under the Act.

10. Right of First Refusal on Dispositions of Vested Shares.

a. Receipt of Third-Party Offer. If at any time Employee desires to sell for cash, cash equivalents or any other form of consideration (including a promissory note) Vested Shares pursuant to an offer or proposed offer from a third party (the "Proposed Transferee"), Employee shall submit a written offer (the "Offer") to sell such Vested Shares (the "Offered Shares") to the Company on terms and conditions, including price, not less favorable to the Company than those on which Employee proposes to sell such Offered Shares to the Proposed Transferee. The Offer shall disclose the identity of the Proposed Transferee, the number of Offered Shares proposed to be sold, the total number of Vested Shares owned by Employee, the terms and conditions, including price, of the proposed sale, and any other material facts relating to the proposed sale. The Offer shall further state that the Company may acquire, in accordance with the provisions of this Agreement, all or any portion of the Offered Shares for the price and upon the other terms and conditions, including deferred payment (if applicable), set forth therein.

b. Company Notice of Intent to Purchase. If the Company desires to purchase all or any portion of the Offered Shares, the Company shall give to Employee written notice of the number of Offered Shares to be purchased by it within 30 days of the date of the Offer. Such communication shall, when taken in conjunction with the Offer, be deemed to constitute a valid,

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legally binding and enforceable agreement for the sale and purchase of the Offered Shares. Sale of the Offered Shares to the Company pursuant to this Section 10 shall be made at the offices of the Company on the 45th day following the date of the Offer (or, if such day is not a business day, then on the next succeeding business day). Such sale shall be effected by Employee's delivery to the Company of a certificate or certificates evidencing the Offered Shares to be purchased by the Company, duly endorsed for transfer to the Company, against payment to Employee of the purchase price therefor by the Company by a certified or cashier's check.

c. Sale to Third Party. If, within 30 days of its receipt of notice of the Offer, the Company fails to deliver written notice to Employee of its intention to purchase all of the Offered Shares (the Offered Shares which the Company does not elect to purchase being referred to as the "Refused Shares"), the Refused Shares not so purchased may be sold by Employee at any time within 90 days after the date of the Offer, at not less than the price and upon other terms and conditions, if any, not more favorable to the Proposed Transferee than those specified in the Offer. If the Refused Shares are not sold within such 90 day period, they shall continue to be subject to the requirements of a prior offer pursuant to this Section 10. If the Refused Shares are sold pursuant to this section 10 to any purchaser who is not a party to an agreement with the Company containing restrictions on the transfer of the Vested Shares to the same extent as those contained herein, the Company, may at its option, require the purchaser of Vested Shares the same as those set forth in this Agreement.

d. Permitted Transfers. Employee shall have the right to make Permitted Transfers (as defined below) of Employee's Vested Shares and the provisions of subsections (a), (b) and (c) above shall not apply to any such Permitted Transfer by Employee. For purposes of this Agreement, "Permitted Transfer" shall mean any transfer by Employee during his or her lifetime of all or any portion of the Vested Shares (i) to the Company; or (ii) to any parent, spouse, child, grandchild, brother, sister or the spouse of a child, grandchild, brother or sister (a "Member of the Immediate Family") of Employee, to a trust created for the benefit of a Member of the Immediate Family of Employee or to a custodian of a property of one or more such persons, or to a limited partnership or limited liability company all partners or members of which are Members of the Immediate Family of Employee, any of such transfers to include transfers by will or the laws of descent and distribution; provided, however, that, it shall be a condition of each such transfer, that (x) the transferee agrees to be bound by the terms of this Agreement, including without limitation Sections 10, 11 and 13, as though no such transfer had taken place, and that (y) Employee has complied with all applicable laws in connection with such transfer.

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## 11. Right of Repurchase of Vested Shares.

a. Termination of Employment Relationship. If Employee's employment or other service relationship with the Company terminates, voluntarily or involuntarily, for any reason, the Company shall have the right to purchase, and Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement) shall, at the election of the Company, be obligated to sell, all or any part of Employee's Vested Shares at the purchase price and on the terms provided in this Section 11 (the "Repurchase Right").

b. Exercise of Repurchase Right. The Company may exercise the Repurchase Right by giving to Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement), within 30 days of the date on which Employee's employment or other service relationship with the Company terminates (the "Termination Date"), written notice of (i) the number of Vested Shares to be purchased by it, and (ii) the purchase price, as determined in a manner provided below, to be paid for such Vested Shares. Such communication shall be deemed to constitute a valid, legally binding and enforceable agreement for the sale and purchase of the Vested Shares.

The purchase price of Vested Shares purchased by the Company pursuant to this Section 11 shall be the fair market value of such Vested Shares on the Termination Date, as conclusively determined by the Board of Directors of the Company after taking into consideration such factors as it deems appropriate.

Sale of the Vested Shares to the Company pursuant to this Section 11 shall be made at the offices of the Company on the 45th day following the Termination Date (or, if such day is not a business day, then on the next succeeding business day) or such earlier business day of which the Company shall notify Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement). Such sale shall be effected by the delivery to the Company of a certificate or certificates evidencing the Vested Shares to be purchased by the Company, duly endorsed for transfer to the Company, against payment to Employee (or Employee's legal representative or transferee(s) pursuant to Section 10(d) of this Agreement) of the purchase price therefor by the Company by a certified or cashier's check.

12. Effect of Prohibited Transfer. The Company shall not be required (a) to transfer on its books any Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Agreement, or (b) to treat as owner of such Shares or to pay dividends to any transferee to whom any such Shares shall have been so sold or transferred.

13. Initial Public Offering. Upon the closing of the first underwritten public offering by the Company under the Act of its Stock for its own account for cash: (a) Sections 9(a), 10 and 11 of this Agreement shall terminate except as to Offers accepted and Repurchase Rights exercised by the Company prior to such date; (b) without the prior written approval of the Company, Employee agrees not to, directly or indirectly, make or cause any offering, sale, short sale, hypothecation, pledge or other disposition of any Vested Shares until the date 180 days after the effective date of the registration statement filed with the Securities and Exchange Commission pursuant to the Act by the Company in connection with such offering (the "Holdback Period"); and (c) Employee shall, if so requested by the Company, sign an agreement with the

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underwriters of the offering containing such terms and provisions requested by such underwriters substantially similar to those contained in this Section 13. The Company may impose stop-transfer instructions with respect to the Shares or other securities subject to the foregoing restrictions until the end of the Holdback Period.

14. Termination of Restrictions on Transfer. The restrictions on the transfer of Vested Shares contained in Sections 11 through 13 of this Agreement, and the obligations of Employee and the Company set forth therein, except as to Offers accepted and Repurchase Rights exercised by the Company prior to a Change in Control, shall terminate upon a Change in Control, as defined below. The transfer of the Shares pursuant to a Change in Control shall not be subject to the provisions of Sections 9(a) and 10 of this Agreement.

For purposes of this Section 14, Change in Control shall mean:

(i) the acquisition by any Person or group of the ultimate beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of more than 50% of the then outstanding securities of the Company entitled to vote generally in the election of directors; excluding, however, the following: (A) any acquisition directly from the Company (excluding any acquisition by virtue of the exercise of an exercise, conversion or exchange privilege unless the security being so exercised, converted or exchanged was itself acquired directly from the Company), (B) any acquisition by the Company, or (C) any acquisition by an employee benefit plan (or related trust) sponsored or maintained by the Company or by any corporation controlled by the Company; or

(ii) a reorganization, recapitalization, merger or consolidation (a "Corporate Transaction") of the Company, unless securities representing more than 50% of the then outstanding securities entitled to vote generally in the election of directors of the Company or the corporation resulting from or surviving such Corporate Transaction (or the ultimate parent of the Company or such corporation after such Corporate Transaction) are beneficially owned subsequent to such Corporate Transaction by the Person or Persons who were the beneficial owners of the outstanding securities of the Company entitled to vote generally in the election of directors immediately prior to such Corporate Transaction, in substantially the same proportions as their ownership immediately prior to such Corporate Transaction; or

(iii) the sale, transfer or other disposition of all or substantially all of the assets of the Company; or

(iv) the dissolution or liquidation of the Company.

For purposes of this definition, securities entitled to vote generally in the election of directors that are issuable upon exercise of an exercise, conversion or exchange privilege shall be deemed to be outstanding. In addition, for purposes of this definition the following terms have the meanings set forth below:

A Person will be deemed to be the "owner" of any securities of which such Person would be the "beneficial owner," as such term is defined in Rule 13d-3 promulgated by the Securities and Exchange Commission under the Exchange Act.

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"Person" has the meaning used in Section 13(d) of the Exchange Act, except that "Person" does not include the Company or a wholly owned subsidiary of the Company or an employee benefit plan (or related trust) of the Company or of a wholly owned subsidiary.

15. Certain Tax Matters. Employee expressly acknowledges the following:

a. Employee has been advised to confer promptly with a professional tax advisor to consider whether Employee should make a so-called "83(b) election" with respect to the Shares. Any such election, to be effective, must be made in accordance with applicable regulations and within thirty (30) days following the date of this Award. The Company has made no recommendation to Employee with respect to the advisability of making such an election.

b. The award or vesting of the Shares acquired hereunder, and the payment of dividends with respect to such Shares, may give rise to "wages" subject to withholding. Employee expressly acknowledges and agrees that Employee's rights hereunder are subject to Employee's promptly paying to the Company in cash (or by such other means as may be acceptable to the Company in its discretion, including, if the administrator of the Plan so determines, by the delivery of previously acquired Stock or shares of Stock acquired hereunder or by the withholding of amounts from any payment hereunder) all taxes required to be withheld in connection with such award, vesting or payment.

16. No Employment Rights. Nothing in the Plan, the Award or this Agreement confers upon the Employee any right to continued employment or interferes with the right of the Company to terminate Employee's employment at any time.

17. Severability; Governing Law. If any provisions of this Agreement shall be determined to be illegal or unenforceable by any court of law, the remaining provisions shall be severable and enforceable in accordance with their terms. This Agreement shall be governed by, and construed in accordance with, the laws of Delaware, excluding its choice of law provisions.

18. Injunctive Relief. It is acknowledged that it will be impossible to measure the damages that would be suffered by the Company if Employee fails to comply with the provisions of this Agreement and that, in the event of any such failure, the Company will not have an adequate remedy at law. The Company shall, therefore, be entitled to obtain specific performance of each of Employee's obligations hereunder and to obtain immediate injunctive relief without the requirement of posting a bond. Employee shall not urge, as a defense to any proceeding for such specific performance or injunctive relief, that the Company has an adequate remedy at law.

19. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors and permitted assigns.

20. Amendments. Except as provided below, the Board may at any time or times amend the Plan or this Agreement for the purpose of satisfying the requirements of any changes in applicable laws or regulations or for any other purpose which at the time may be permitted by law. Sections 9 through 11 of this Agreement, containing restrictions on the transfer of Shares, may be amended or modified only by a written instrument executed by both the Company and Employee. No termination or amendment of the Plan or amendment of this Agreement shall,

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without Employee's consent, adversely affect Employee's rights under the Plan or this Agreement.

21. Notices. All notices required or permitted hereunder shall be in writing and deemed effectively given upon personal delivery, upon deposit with the United States Post Office, by registered or certified mail, postage prepaid, or upon deposit with a recognized express overnight courier service, addressed, if to the Company, to 400 Pleasant Street, Watertown, MA 02472, attention: Chief Financial Officer, and if to Employee, to the address shown beneath his or her respective signature to this Agreement, or at such other address or addresses as either party shall designate to the other in accordance with this Section 21.

22. Merger Provision. This Agreement, including the Plan which is incorporated herein by reference in its entirety, constitutes the entire agreement between the parties hereto pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements and understandings, whether oral or written, of the parties hereto concerning the subject matter hereof.

23. Waivers. Any provision contained in this Agreement may be waived, either generally or in any particular instance, by the Company.

24. Definition. As used in this Agreement, the term "Company" shall include any subsidiary or parent of the Company as defined in Sections 424(e) and (f) of the Code.

25. Consistency with Plan. If there is any inconsistency between the provisions of this Agreement and the provisions of the Plan, the Plan shall control.

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Name of Employee: Lori Freedman

Number of Shares of Restricted Stock granted: 20,000

Date of Grant: August 16, 2004

The foregoing Restricted Stock Award is hereby accepted and in consideration of the grant of such Award, the undersigned Employee hereby agrees with Control Delivery Systems, Inc. that the undersigned will be bound by the foregoing Restricted Stock Award Agreement:

/s/ Lori Freedman

- ----- (Signature of Employee)

Dated: \_\_\_\_\_, 2004

September 29, 2005

PAUL ASHTON

#### DEAR DR. ASHTON:

As you know, Control Delivery Systems, Inc. (the "Company") is contemplating certain strategic transactions, including a possible sale or merger involving the Company and pSvida Ltd. (the "Potential Acquiror"). There is no assurance that the Company will enter into an agreement with respect to any such transaction or consummate any such transaction even if such an agreement is reached. However, the Company has been advised that the prospects of a combination with the Potential Acquiror would be advanced if you and certain other key personnel were to agree to certain undertakings designed to assure the continuation of your services to the Company for at least a transition period following any such combination. The Company believes that the terms of this letter agreement (this "Retention Agreement") will be in the best interests both of you and the shareholders of the Company by assisting in the realization of the proposed combination.

The terms of this Retention Agreement set forth herein are as follows:

The Company and you are parties to a restricted stock award agreement or agreements (the "Stock Agreements") pursuant to which you currently hold 20,000 shares of common stock of the Company that is subject to a substantial risk of forfeiture (the "Restricted Stock"). Schedule A hereto lists the Restricted Stock shares that you hold and the dates on which those shares were awarded to you. Notwithstanding the provisions of the Stock Agreements or any other agreement between you and the Company to the contrary, you hereby agree that the following vesting and forfeiture rules shall apply:

(a) Except as hereinafter provided, the Restricted Stock subject to the Stock Agreements, including your rights to any cash or property paid with respect thereto or exchanged therefor in connection with a Liquidity Event, or thereafter, (the Restricted Stock and such other securities, cash, property or other rights, if any, being herein referred to as the "Restricted Property") shall vest on the date that is six (6) months after the Liquidity Event Date if you are then employed by the Company or its successor (or a parent or subsidiary thereof) (the "Employer"); provided, that if there has been no Liquidity Event Date by December 31, 2005, the Restricted Property shall vest on June 30, 2006 if you are then still employed by the Employer. The applicable vesting date described in the preceding sentence is hereinafter referred to as the "Scheduled Vesting Date." For purposes of this Retention Agreement, the terms "Liquidity Event" and "Liquidity Event Date" shall have the meaning set forth in the Stock Agreements.

(b) On the Liquidity Event Date relating to the transaction with the Potential Acquiror you will be granted shares (American Depository Shares or American Depository Receipts, hereinafter "ADSs") of the common equity of the Potential Acquiror traded in the U.S. having a fair market value on the date of closing equal to \$110,000.00 (the "Additional Shares"). The Additional Shares shall be subject to the

same restrictions as the Restricted Property and shall be treated for all purposes of this Retention Agreement as the Restricted Property. For purposes of this Retention Agreement, "fair market value" means the average of the closing price of pSivida ADSs on the Nasdaq National Market for each of the ten (10) trading days ending on the trading day that is four (4) full trading days prior to the Liquidity Event Date.

(c) Subject to the following sentence, if your employment with the Employer terminates for any reason prior to the Scheduled Vesting Date all of your Restricted Property shall be automatically and immediately forfeited or vested to the extent provided in the Stock Agreements, Amended and Restated Control Delivery Systems Change of Control Agreement dated August 17, 2004 (the "Change of Control Agreement") and Severance Agreement dated February 20, 2004, as amended (the "Severance Agreement"), except that in applying the provisions of such agreements the Restricted Property shall not be deemed to be vested merely because the Stock Agreements would have provided for scheduled vesting earlier than the Scheduled Vesting Date. Notwithstanding the foregoing, if your employment with the Employer is (i) involuntarily terminated, other than for "Cause" as hereinafter defined, by the Employer, or (ii) terminated by the Participant for "Good Reason" as hereinafter defined, in either case prior to the Scheduled Vesting Date, all of your Restricted Property shall be treated for all purposes as having vested in full immediately prior to such termination of employment. For purposes of the preceding sentence, "Cause" and "Good Reason" shall have the meanings assigned to them in your Change of Control Agreement.

Upon the occurrence of the Liquidity Event Date the sections of your Stock Agreements captioned "Restrictions on Transfer of Vested Shares" (paragraph (a) only), "Right of First Refusal on Dispositions of Vested Shares" and "Right of Repurchase of Vested Shares" shall be of no further force and effect.

Except as expressly provided in this Retention Agreement, the terms of your Stock Agreements, Change of Control Agreement, Severance Agreement and other agreements, if any, with the Employer shall remain in full force and effect.

Nothing in this Retention Agreement shall be construed as either limiting or expanding such rights, if any, as you may have to continued employment with the Employer.

This Retention Agreement shall be binding on and enforceable against the Company and its successors and assigns and upon and against you and your heirs and assigns.

This Retention Agreement shall be construed in accordance with the laws of the Commonwealth of Massachusetts, except for the conflicts of laws provisions thereof.

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If you agree with the terms of this Retention Agreement, please so indicate by signing the enclosed copy of this Retention Agreement in the space indicated below and returning the enclosed copy to Cristin Rothfuss, whereupon this Retention Agreement shall take effect as of the date first set forth above as an agreement under seal.

CONTROL DELIVERY SYSTEMS, INC.

By: /s/ Michael J. Soja /s/ Paul Ashton Paul Ashton

The undersigned pSvida Limited hereby acknowledges its obligations hereunder as the Potential Acquiror in the event that a Liquidity Event involving pSivida occurs and agrees to be bound by this Agreement and to perform such obligations upon and after the closing of a Liquidity Event involving pSivida.

PSIVIDA LIMITED

By: /s/ Gavin Rezos

Name: Gavin Rezos Title: Managing Director

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Restricted Stock

A. 20,000 Shares Issued on 08/16/04

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September 29, 2005

#### MICHAEL SOJA

DEAR MR. SOJA:

As you know, Control Delivery Systems, Inc. (the "Company") is contemplating certain strategic transactions, including a possible sale or merger involving the Company and pSvida Ltd. (the "Potential Acquiror"). There is no assurance that the Company will enter into an agreement with respect to any such transaction or consummate any such transaction even if such an agreement is reached. However, the Company has been advised that the prospects of a combination with the Potential Acquiror would be advanced if you and certain other key personnel were to agree to certain undertakings designed to assure the continuation of your services to the Company for at least a transition period following any such combination. The Company believes that the terms of this letter agreement (this "Retention Agreement") will be in the best interests both of you and the shareholders of the Company by assisting in the realization of the proposed combination.

The terms of this Retention Agreement set forth herein are as follows:

The Company and you are parties to a restricted stock award agreement or agreements (the "Stock Agreements") pursuant to which you currently hold 20,000 shares of common stock of the Company that is subject to a substantial risk of forfeiture (the "Restricted Stock"). Schedule A hereto lists the Restricted Stock shares that you hold and the dates on which those shares were awarded to you. Notwithstanding the provisions of the Stock Agreements or any other agreement between you and the Company to the contrary, you hereby agree that the following vesting and forfeiture rules shall apply:

(a) Except as hereinafter provided, the Restricted Stock subject to the Stock Agreements, including your rights to any cash or property paid with respect thereto or exchanged therefor in connection with a Liquidity Event, or thereafter, (the Restricted Stock and such other securities, cash, property or other rights, if any, being herein referred to as the "Restricted Property") shall vest on the date that is six (6) months after the Liquidity Event Date if you are then employed by the Company or its successor (or a parent or subsidiary thereof) (the "Employer"); provided, that if there has been no Liquidity Event Date by December 31, 2005, the Restricted Property shall vest on June 30, 2006 if you are then still employed by the Employer. The applicable vesting date described in the preceding sentence is hereinafter referred to as the "Scheduled Vesting Date." For purposes of this Retention Agreement, the terms "Liquidity Event" and "Liquidity Event Date" shall have the meaning set forth in the Stock Agreements.

(b) On the Liquidity Event Date relating to the transaction with the Potential Acquiror you will be granted shares (American Depository Shares or American Depository Receipts, hereinafter "ADSs") of the common equity of the Potential Acquiror traded in the U.S. having a fair market value on the date of closing equal to \$122,497.00 (the "Additional Shares"). The Additional Shares shall be subject to the

same restrictions as the Restricted Property and shall be treated for all purposes of this Retention Agreement as the Restricted Property. For purposes of this Retention Agreement, "fair market value" means the average of the closing price of pSivida ADSs on the Nasdaq National Market for each of the ten (10) trading days ending on the trading day that is four (4) full trading days prior to the Liquidity Event Date.

(c) Subject to the following sentence, if your employment with the Employer terminates for any reason prior to the Scheduled Vesting Date all of your Restricted Property shall be automatically and immediately forfeited or vested to the extent provided in the Stock Agreements, Amended and Restated Control Delivery Systems Change of Control Agreement dated August 17, 2004 (the "Change of Control Agreement") and Severance Agreement dated February 20, 2004, as amended (the "Severance Agreement"), except that in applying the provisions of such agreements the Restricted Property shall not be deemed to be vested merely because the Stock Agreements would have provided for scheduled vesting earlier than the Scheduled Vesting Date. Notwithstanding the foregoing, if your employment with the Employer is (i) involuntarily terminated, other than for "Cause" as hereinafter defined, by the Employer, or (ii) terminated by the Participant for "Good Reason" as hereinafter defined, in either case prior to the Scheduled Vesting Date, all of your Restricted Property shall be treated for all purposes as having vested in full immediately prior to such termination of employment. For purposes of the preceding sentence, "Cause" and "Good Reason" shall have the meanings assigned to them in your Change of Control Agreement.

Upon the occurrence of the Liquidity Event Date the sections of your Stock Agreements captioned "Restrictions on Transfer of Vested Shares" (paragraph (a) only), "Right of First Refusal on Dispositions of Vested Shares" and "Right of Repurchase of Vested Shares" shall be of no further force and effect.

Except as expressly provided in this Retention Agreement, the terms of your Stock Agreements, Change of Control Agreement, Severance Agreement and other agreements, if any, with the Employer shall remain in full force and effect.

Nothing in this Retention Agreement shall be construed as either limiting or expanding such rights, if any, as you may have to continued employment with the Employer.

This Retention Agreement shall be binding on and enforceable against the Company and its successors and assigns and upon and against you and your heirs and assigns.

This Retention Agreement shall be construed in accordance with the laws of the Commonwealth of Massachusetts, except for the conflicts of laws provisions thereof.

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If you agree with the terms of this Retention Agreement, please so indicate by signing the enclosed copy of this Retention Agreement in the space indicated below and returning the enclosed copy to Cristin Rothfuss, whereupon this Retention Agreement shall take effect as of the date first set forth above as an agreement under seal.

CONTROL DELIVERY SYSTEMS, INC.

By: /s/ Lori Freedman /s/ Michael J.Soja Michael J.Soja

The undersigned pSvida Limited hereby acknowledges its obligations hereunder as the Potential Acquiror in the event that a Liquidity Event involving pSivida occurs and agrees to be bound by this Agreement and to perform such obligations upon and after the closing of a Liquidity Event involving pSivida.

PSIVIDA LIMITED

By: /s/ Gavin Rezos

Name: Gavin Rezos Title: Managing Director

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SCHEDULE A

## Restricted Stock

1.	20,000	Shares	Issued	on	08/16/04			
2.	60,040	Shares	Issued	on	10/20/04	derived from:		
3.	14,040	Shares	issued	on	05/28/03	(transferred to	above	grant)
4.	36,000	Shares	issued	on	10/07/03	(transferred to	above	grant)
5.	10,000	Shares	issued	on	10/07/03	(transferred to	above	grant)

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#### LORI FREEDMAN

## DEAR LORI FREEDMAN:

As you know, Control Delivery Systems, Inc. (the "Company") is contemplating certain strategic transactions, including a possible sale or merger involving the Company and pSvida Ltd. (the "Potential Acquiror"). There is no assurance that the Company will enter into an agreement with respect to any such transaction or consummate any such transaction even if such an agreement is reached. However, the Company has been advised that the prospects of a combination with the Potential Acquiror would be advanced if you and certain other key personnel were to agree to certain undertakings designed to assure the continuation of your services to the Company for at least a transition period following any such combination. The Company believes that the terms of this letter agreement (this "Retention Agreement") will be in the best interests both of you and the shareholders of the Company by assisting in the realization of the proposed combination.

The terms of this Retention Agreement set forth herein are as follows:

The Company and you are parties to a restricted stock award agreement or agreements (the "Stock Agreements") pursuant to which you currently hold 20,000 shares of common stock of the Company that is subject to a substantial risk of forfeiture (the "Restricted Stock"). Schedule A hereto lists the Restricted Stock shares that you hold and the dates on which those shares were awarded to you. Notwithstanding the provisions of the Stock Agreements or any other agreement between you and the Company to the contrary, you hereby agree that the following vesting and forfeiture rules shall apply:

(a) Except as hereinafter provided, the Restricted Stock subject to the Stock Agreements, including your rights to any cash or property paid with respect thereto or exchanged therefor in connection with a Liquidity Event, or thereafter, (the Restricted Stock and such other securities, cash, property or other rights, if any, being herein referred to as the "Restricted Property") shall vest on the date that is six (6) months after the Liquidity Event Date if you are then employed by the Company or its successor (or a parent or subsidiary thereof) (the "Employer"); provided, that if there has been no Liquidity Event Date by December 31, 2005, the Restricted Property shall vest on June 30, 2006 if you are then still employed by the Employer. The applicable vesting date described in the preceding sentence is hereinafter referred to as the "Scheduled Vesting Date." For purposes of this Retention Agreement, the terms "Liquidity Event" and "Liquidity Event Date" shall have the meaning set forth in the Stock Agreements.

(b) On the Liquidity Event Date relating to the transaction with the Potential Acquiror you will be granted shares (American Depository Shares or American Depository Receipts, hereinafter "ADSs") of the common equity of the Potential Acquiror traded in the U.S. having a fair market value on the date of closing equal to \$132,497.00 (the "Additional Shares"). The Additional Shares shall be subject to the

same restrictions as the Restricted Property and shall be treated for all purposes of this Retention Agreement as the Restricted Property. For purposes of this Retention Agreement, "fair market value" means the average of the closing price of pSivida ADSs on the Nasdaq National Market for each of the ten (10) trading days ending on the trading day that is four (4) full trading days prior to the Liquidity Event Date.

(c) Subject to the following sentence, if your employment with the Employer terminates for any reason prior to the Scheduled Vesting Date all of your Restricted Property shall be automatically and immediately forfeited or vested to the extent provided in the Stock Agreements, Amended and Restated Control Delivery Systems Change of Control Agreement dated August 17, 2004 (the "Change of Control Agreement") and Severance Agreement dated February 20, 2004, as amended (the "Severance Agreement"), except that in applying the provisions of such agreements the Restricted Property shall not be deemed to be vested merely because the Stock Agreements would have provided for scheduled vesting earlier than the Scheduled Vesting Date. Notwithstanding the foregoing, if your employment with the Employer is (i) involuntarily terminated, other than for "Cause" as hereinafter defined, by the Employer, or (ii) terminated by the Participant for "Good Reason" as hereinafter defined, in either case prior to the Scheduled Vesting Date, all of your Restricted Property shall be treated for all purposes as having vested in full immediately prior to such termination of employment. For purposes of the preceding sentence, "Cause" and "Good Reason" shall have the meanings assigned to them in your Change of Control Agreement.

Upon the occurrence of the Liquidity Event Date the sections of your Stock Agreements captioned "Restrictions on Transfer of Vested Shares" (paragraph (a) only), "Right of First Refusal on Dispositions of Vested Shares" and "Right of Repurchase of Vested Shares" shall be of no further force and effect.

Except as expressly provided in this Retention Agreement, the terms of your Stock Agreements, Change of Control Agreement, Severance Agreement and other agreements, if any, with the Employer shall remain in full force and effect.

Nothing in this Retention Agreement shall be construed as either limiting or expanding such rights, if any, as you may have to continued employment with the Employer.

This Retention Agreement shall be binding on and enforceable against the Company and its successors and assigns and upon and against you and your heirs and assigns.

This Retention Agreement shall be construed in accordance with the laws of the Commonwealth of Massachusetts, except for the conflicts of laws provisions thereof.

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If you agree with the terms of this Retention Agreement, please so indicate by signing the enclosed copy of this Retention Agreement in the space indicated below and returning the enclosed copy to Cristin Rothfuss, whereupon this Retention Agreement shall take effect as of the date first set forth above as an agreement under seal.

CONTROL DELIVERY SYSTEMS, INC.

By: /s/ Michael Soja /s/ Lori Freedman Lori Freedman

The undersigned pSvida Limited hereby acknowledges its obligations hereunder as the Potential Acquiror in the event that a Liquidity Event involving pSivida occurs and agrees to be bound by this Agreement and to perform such obligations upon and after the closing of a Liquidity Event involving pSivida.

PSIVIDA LIMITED

By: /s/ Gavin Rezos

Name: Gavin Rezos Title: Managing Director

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SCHEDULE A

## Restricted Stock

1.	20,000	shares	Issued	on	08/16/04					
2.	51,700	shares	Issued	on	10/20/04					
3.	11,700	shares	issued	on	05/28/03	(transferred	to	above	grant)	
4.	30,000	shares	issued	on	10/07/03	(transferred	to	above	grant)	
5.	10,000	shares	issued	on	10/07/03	(transferred	to	above	grant)	

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## NON-COMPETITION AGREEMENT

IN CONSIDERATION of and as a condition to my (i) receiving consideration pursuant to the terms of the Agreement and Plan of Merger, dated October 3, 2005 (the "MERGER AGREEMENT") by and among pSivida Limited ("PARENT"), pSivida Inc. and Control Delivery Systems, Inc. (the "COMPANY"), and (ii) receiving an offer of employment with Parent consistent with the terms set forth in Section 2(b) below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, I, Paul Ashton (referred to herein as "I", "ME" or as "EXECUTIVE"), agree with Parent as follows:

1. DEFINITIONS.

(a) "AGREEMENT" shall mean this Non-Competition Agreement.

(b) "CAUSE" shall mean, in respect of the termination of Executive's employment by Parent, (a) willful malfeasance, gross misconduct or gross negligence in the performance by Executive of the duties of his position that has a material adverse effect on the Parent, (b) the material breach by Executive of Sections 3(a), 4, 5 or 6 of this Agreement, (c) fraud or dishonesty by Executive with respect to Parent or any of its affiliates or his employment, (d) Executive's conviction of any crime that involves deception, fraud or moral turpitude or any felony (including, in each case, entry of a guilty or nolo contendere plea, and, excluding traffic violations or similar minor offenses), or (e) repeated or prolonged absence from work by Executive other than for illness, Disability or authorized vacation. Parent may treat a termination of Executive's employment as termination for Cause only after (i) giving Executive written notice of the intention to terminate for Cause, including a description of the conduct that the Parent believes constitutes the basis for a Cause termination, and of his right to a hearing by Parent's Board of Directors (the "Board"), (ii) in the event of a termination under clause (a), (b) or (e) above, providing Executive a 30-day period in which to cure the conduct giving rise to the Parent's notice of a Cause termination, unless, with respect to clause (a) and (b) above, (I) in Parent's reasonable judgment, protective action inconsistent with such cure period (e.g., immediate termination) is necessary to avoid harm to Parent or (II) Parent reasonably determines that Executive's conduct is egregious, in which event, Parent may shorten the cure period or terminate Executive's employment immediately (subject to the requirements set forth in clauses (iii) and (iv) below), (iii) at least 30 days after giving the notice, conducting a hearing by the Board at which Executive may be represented by counsel, and (iv) giving Executive written notice of the results of the hearing and the factual basis for the Board's determination of Cause, which shall require a vote of a majority of the members of the Board then in office other than Executive. Except in connection with Executive's opportunity, if any, to cure the conduct giving rise to Parent's notice of termination for Cause as set forth in clause (ii) above, nothing in the foregoing sentence shall prevent Parent from terminating Executive's employment pending any determination of Cause as set forth in the foregoing sentence, any such determination shall be retroactive to the date of termination, and Parent shall not be obligated to compensate Executive hereunder for the period from such termination until such time as a determination by Parent's Board of Directors that such termination was not for Cause. Notwithstanding the foregoing, cause shall not include an act or failure to act based on authority given pursuant to a resolution duly adopted by the Board or based on the advice of Parent's General Counsel or willful failure

due to incapacity resulting from Disability or any actual or anticipated failure after Executive provides written notice of a termination for Good Cause.

(c) "CLOSING" shall have the meaning set forth in the Merger Agreement.

(d) "DEVELOPMENTS" shall have the meaning set forth in Section 5(a).

(e) "DISABILITY" shall mean physical or mental incapacity of a nature which prevents Executive, in the professional judgment of Executive's physician or, at Parent's election, a board-certified physician mutually agreed upon by Parent and Executive, from performing the essential functions of Executive's position with Parent with or without a reasonable accommodation for a period of ninety (90) consecutive days or one hundred eighty (180) days during any consecutive 12-month period.

(f) "EFFECTIVE TIME" shall have the meaning set forth in the Merger Agreement.

(g) "GOOD CAUSE" shall mean, in respect of the termination of Executive's employment by Executive, (i) failure by Parent to maintain Executive in the positions of Head of R&D Ophthalmology for the Surviving Company and Executive Director Strategy of Parent, without Executive's consent, (ii) a material diminution of Executive's duties and responsibilities in such positions or a material diminution of Executive's authority with respect to such positions, as described in Section 2(b) hereof and otherwise set forth in the employment agreement referenced therein (assuming the parties execute such employment agreement), excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by Parent promptly after receipt of written notice thereof given by Executive, (iii) a breach by Parent of any material term of this Agreement or the employment agreement referenced in Section 2(b) (assuming the parties execute such employment agreement), or (iv) relocation of Executive's principal place of work to a location more than thirty (30) miles from Executive's address set forth in Section 11(e) below without Executive's consent. Executive may treat a resignation from employment as termination for Good Cause only after (a) giving Parent written notice of the intention to terminate for Good Cause, (b) providing Parent at least 30 days after receipt of such notice to cure the conduct or action giving rise to Good Cause, unless, with respect to clause (i) and (ii), Executive reasonably determines that Parent's conduct is eqregious and has resulted in significant, irreparable harm to Executive, in which event, Executive may shorten the cure period or terminate his employment immediately, and (c) if applicable, Parent has failed to cure the action or conduct giving rise to Good Cause during the 30 day cure period.

(h) "MERGER" shall have the meaning set forth in the Merger Agreement.

(i) "PROPRIETARY INFORMATION" shall have the meaning set forth in Section 4(a).

(j) "REAR-OCULAR DRUG DELIVERY BUSINESS" shall have the meaning set forth in Section 3(b)(i).

(k) "RESTRICTED ACTIVITIES" shall have the meaning set forth in Section 3(b).

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(1) "SURVIVING COMPANY" shall have the meaning set forth in the Merger Agreement.

# 2. EFFECTIVENESS.

(a) This Agreement shall enter into full force and effect as of the Effective Time. In the event that the Merger Agreement is terminated prior to the Effective Time, this Agreement shall be null and void and neither party shall have any rights or obligations hereunder.

(b) Parent represents that, prior to the Effective Time, it shall provide Executive with an employment agreement setting forth the material terms of his employment with Parent as of the Effective Time. Such employment agreement shall include, among other things, the following material terms: (i) a title Head of Research & Development Ophthalmology of the Surviving Company, responsible for duties typically associated with such position; (ii) a title with Parent of Executive Director Strategy, reporting directly to Parent's chief executive officer, responsible for, among other things, the production of overall strategic business and development plans; (iii) a title of interim President of the Surviving Company, responsible for, among other things, ensuring effective communication among Parent business units particularly with respect to milestones and participation in the general management of Parent including regular meetings and discussions with Parent's chief executive officer and chairman; (iv) a compensation package commensurate with other senior executives of Parent, which shall include, without limitation: (A) a base salary of \$300,000 per year, (B) annual discretionary bonus eligibility on terms that are no less favorable than that which Executive was entitled as of the date of this Agreement, (C) entitlement to benefits that are no less favorable than those to which Executive was entitled as of the date of this Agreement, and (D) a grant of options to purchase capital stock in the Parent commensurate with other senior executives of Parent, including without limitation, subject to confirmation of Parent's remuneration committee and shareholder approval, 500,000 options vesting as to half in 12 months and the balance in 24 months, subject to achieving milestones; (v) four (4) weeks paid vacation per calendar year; (vi) a principal work location located no more than thirty (30) miles from Executive's address set forth in Section 11(e) below without Executive's consent; and (vii) eligibility for severance and related post-termination benefits on terms no less favorable to Executive than those set forth in that certain Severance Agreement between Executive and Company dated February 20, 2004, as amended on August 17, 2004 (the "Severance Agreement") and no greater than those set forth in that certain Change in Control Agreement between Executive and Company dated August 17, 2004 (the "Change in Control Agreement"), which shall supercede and/or terminate Executive's entitlement to severance and related post-termination benefits pursuant to the Severance Agreement and the Change in Control Agreement. Parent and Executive agree to negotiate in good faith and use their reasonable best efforts to finalize the employment agreement consistent with the terms of this Agreement and the contracts referenced herein.

(c) If (i) Parent fails to offer Executive an employment agreement consistent with the requirements of Section 2(b), or Parent revokes such offer prior to the Effective Time for any reason and (ii), as a result of any of the above, Executive declines Parent's offer of employment on or before the Effective Time, then (I) this Agreement shall be null and void and neither party shall have any obligations hereunder, and (II) both the Severance Agreement and Change in Control Agreement shall continue to be in effect as of the Effective Time.

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(d) If (i) Parent offers Executive an employment agreement consistent with the requirements of Section 2(b) and (ii) Executive declines Parent's offer of employment for any reason (other than his death or Disability), then (I) this Agreement shall continue in full force and effect as of the Effective Time and (II) the Severance Agreement but not the Change in Control Agreement shall continue to be in effect upon the Effective Time. Such declination by Executive shall be deemed a termination of employment with Parent by Executive for other than Good Cause under Section 3(b) below.

### 3. COVENANT NOT TO COMPETE.

(a) I understand that Parent is engaged worldwide in the development, production and commercialization of drug delivery and other products based on platform technologies. As of the Effective Time, I agree that I will not, during my employment with Parent, render (as a provider of services, consultant or otherwise) any services related to the business of Parent to anyone other than Parent.

(b) In the event of: (i) the termination of my employment with Parent (other than termination by reason of death or Disability) by me for any reason (whether voluntary on my part, or involuntary) other than Good Cause; or (ii) the termination of my employment with Parent (other than termination by reason of death or Disability) by Parent for Cause, I agree that for a period of twelve (12) months from the date of such termination, I will neither:

(i) engage directly for myself, or in conjunction with or on behalf of any person or entity, or otherwise own, manage, operate, control, acquire, hold any interest in, or participate in the ownership, management, operation or control of any person or entity engaged in the development, production or commercialization of systems for the delivery of therapeutic drugs to the tissues in the posterior segment of the eye (the "REAR-OCULAR DRUG DELIVERY BUSINESS"), nor

(ii) work for or become employed by or associated with (in any capacity, including without limitation officer, director, employee, partner, stockholder, owner, member, proprietor, consultant, investor, salesperson, co-owner, trustee, promoter, technician, engineer, analyst, agent, representative, distributor, supplier, lender, advisor or manager) any person or entity that is engaged in the Rear-Ocular Drug Delivery Business (the activities set forth in (i) and (ii) (as modified by the following paragraph) are collectively referred to as the "RESTRICTED ACTIVITIES").

Notwithstanding the foregoing, Parent accepts that nothing in this Section 3(b) shall prevent Executive from and after the date six (6) months after termination of Executive's employment from engaging in activities predominantly academic (and not commercial) in nature, including without limitation teaching, lecturing, writing and publishing articles or engaging in research; provided that (I) unless approved by Parent in writing or otherwise described below, Executive receives no compensation (including without limitation salary, benefits, bonus, profit sharing, dividends, commissions, gifts, gratuities, or any other payments, whether in cash or otherwise, present or future) whatsoever for such activities, other than reimbursement of expenses, for any period in which he is receiving severance payments from the Parent under this Agreement, his employment agreement with Parent or any other agreement between Executive and Parent,

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except where the payment of compensation is required by the academic institution and Executive agrees in writing to donate the full amount of such compensation to a registered charitable organization; and (II) in the course of engaging in such activities Executive does not breach his obligations under this Agreement, including without limitation any obligations under Sections 4 and 5 herein.

Within six (6) months after the termination of my employment for the reasons set forth above, Parent may at its sole discretion extend my obligations under this Section 3(b) for an additional twelve-month period; provided that in such a case Parent will pay me an amount equal to my annual base salary as of the date of termination, to be paid in equal monthly installments over such additional twelve-month period.

(c) In the event of the termination of my employment with Parent (other than termination by reason of death or Disability) (x) by me for Good Cause, or (y) by Parent for any reason other than for Cause, I agree that, at Parent's option, exercisable by written notice given:

- (i) not less than 30 days after Parent receives notice of such termination by me hereunder; and/or
- (ii) at the time of such termination by Parent hereunder; and/or
- (iii) with respect to a follow-on notice to Executive, no later than six months after the termination of my employment with Parent hereunder,

for a period of up to twenty-four (24) months from the date of such termination, as specified in Parent's notice or notices, I will not engage in any Restricted Activities; provided that in such case Parent will pay me an amount equal to 1/24th of \$800,000 for each month in the period specified, which amount may be offset against any severance or other payments owed to me in connection with the termination of my employment as described in this Section 3(c). I understand that any payments made to me pursuant to the preceding sentence are made in consideration of my not engaging in any Restricted Activities or otherwise violating the terms of this Agreement, and that, in addition to any other rights or remedies available to Parent at law or in equity, Parent shall have the right to terminate such payments if, and only if, I engage in Restricted Activities during the specified period or otherwise violate the terms of this Agreement and such conduct continues following my receipt of written notice from the Company that describes the basis for the Company's contention that I have engaged in Restricted Activities or otherwise violated the terms of this Agreement. I understand that the Company may provide more than one written notice to extend the noncompete period under this Section 3(c), provided that such notices are sent within the six (6) month period after the termination of my employment.

(d) My obligations under this Section 3 shall extend to all geographical areas of the world in which Parent, or any of its related companies, is offering its services, either directly or indirectly, through licenses or otherwise, during the time period specified in this Section 3.

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(e) I further agree that while I remain employed by Parent and for the duration of any period during which I am prohibited from engaging in the Restricted Activities pursuant to this Section 3, I will not, on behalf of myself or any other person or entity, (i) compete for, or engage in the solicitation of, or attempt to divert or take away from the Company, Parent or any of their affiliates, any customer of the Company, Parent or any of their affiliates who has done business with the Company, Parent or any of their affiliates, as the case may be, during the period of my employment by Parent; (ii) compete for, solicit or attempt to divert or take away from the Company, Parent or any of their affiliates, any prospective customer that has within the twelve (12) month period prior to such termination, expressed an interest in doing business with the Company, Parent or any of their affiliates and about which I learned during my employment with Parent; or (iii) hire or engage or attempt to hire or engage any individual, or attempt to induce an individual to terminate their employment or other service arrangement, who was an employee of or other service provider to the Company, Parent or any of their affiliates at any time during the twelve (12) month period prior to my termination from employment.

(f) Further, while I remain employed by Parent and for the duration of any period during which I am prohibited from engaging in the Restricted Activities pursuant to this Section 3, I shall not, directly or indirectly, make or cause to be made to any Person any disparaging, derogatory or other negative statement about the Company, Parent or any of their affiliates, including their businesses, products, services, policies, practices, operations, employees, sales representatives, agents, officers, members, managers or directors. Similarly, during the period set forth in the preceding sentence, Parent shall not and shall not authorize or encourage any members of its Board of Directors or employees to directly or indirectly, make or cause to be made to any person any disparaging, derogatory or other negative statement about Executive, including the performance of his duties on behalf of the Company or the circumstances surrounding his separation from employment.

(g) I REPRESENT AND WARRANT THAT THE KNOWLEDGE, SKILLS AND ABILITIES I POSSESS ARE SUFFICIENT TO PERMIT ME, IN THE EVENT OF TERMINATION OF MY EMPLOYMENT WITH PARENT FOR ANY REASON, TO EARN, FOR A PERIOD OF UP TO TWENTY-FOUR (24) MONTHS FROM SUCH TERMINATION, A LIVELIHOOD SATISFACTORY TO ME WITHOUT VIOLATING ANY PROVISION OF SECTION 3 HEREOF, FOR EXAMPLE BY USING SUCH KNOWLEDGE, SKILLS AND ABILITIES, OR SOME OF THEM, IN THE SERVICE OF A PERSON OR ENTITY WHO OR WHICH DOES NOT COMPETE WITH PARENT AS DESCRIBED HEREIN.

#### 4. PROPRIETARY INFORMATION.

(a) I agree that all information and know-how, whether or not in writing, of a private, secret or confidential nature concerning the Company, Parent or any of their affiliates or their respective businesses, financial affairs or operations (collectively, "PROPRIETARY INFORMATION") is and shall be the exclusive property of the Company, Parent or any of their affiliates, as the case may be. By way of illustration, but not limitation, Proprietary Information may include inventions, products, manufacturing and other processes, methods, techniques, formulas, compositions, compounds, projects, developments, plans, research data, financial data, personnel data, computer programs, and customer and supplier lists. I will not disclose any Proprietary Information to others outside the Company, Parent or any of their affiliates, provided

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that my obligation not to disclose shall not apply to any information that (i) has become generally available to the public other than as a result of a breach by Executive of his obligations hereunder, (ii) may be required or appropriate in response to any summons or subpoena or in connection with any litigation, or investigation or review by any governmental agency or authority and (iii) must be disclosed in order to comply with any law, order, regulation or ruling applicable to Executive. I will not use any Proprietary Information for any purposes other than my work for the Company, Parent or any of their affiliates, without prior written approval by the Board of Directors of Parent, either during or after my providing services. If I have any questions as to what constitutes Proprietary Information, I will consult with the Board of Directors for this purpose.

(b) I agree that all files, letters, memoranda, reports, records, data, sketches, drawings, program listings, or other written, photographic, or other tangible material containing Proprietary Information, whether created by me or others, which shall come into my custody or possession, shall be and are the exclusive property of the Company, Parent or any of their affiliates, as the case may be, to be used by me only in the performance of my duties for Parent. All such records or copies thereof and all tangible property of the Company, Parent or any of their affiliates in my custody or possession shall be delivered to Parent within ten (10) calendar days from the earlier of (i) a request by Parent or (ii) termination of my providing services to Parent. After such delivery, I shall not retain any such records or copies thereof or any such tangible property.

(c) I agree that my obligation not to disclose or to use information, know-how and records of the types set forth in paragraphs (a) and (b) above, and my obligation to return records and tangible property, set forth in paragraph (b) above, also extends to such types of information, know-how, records and tangible property of customers of the Company, Parent or any of their affiliates or suppliers to the Company, Parent or any of their affiliates or other third parties who may have disclosed or entrusted the same to Parent or to me in the course of Parent's business with an expectation or understanding that such information was to be maintained as confidential.

### 5. DEVELOPMENTS.

(a) I will make full and prompt disclosure to Parent of all inventions, improvements, discoveries, methods, developments, products, processes, techniques, formulas, compositions, compounds, software, works of authorship and all ideas for trademarks, trade-names and the like, related in any way to the Parent's current, planned or potential products or services, whether patentable or not and whether copyrightable or not, which are created, made, conceived or reduced to practice by me or under my direction or jointly with others during my employment by Parent, whether or not during normal working hours or on the premises of Parent (all of which are collectively referred to in this Agreement as "DEVELOPMENTS").

(b) Except as hereinafter provided, I agree to assign and do hereby assign to Parent (or any person or entity designated by Parent) all my right, title and interest in and to all Developments and all related patents, patent applications, copyrights and copyright applications. I expressly agree that all of my Developments capable of protection under copyright laws shall be deemed and are works made for hire with the understanding that Parent shall own all of the

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exclusive rights to such developments under the United States Copyright Act and all international copyright conventions and foreign laws, and any successor laws thereto.

(c) I agree to cooperate fully with Parent, both during and after my employment with Parent, with respect to the procurement, maintenance and enforcement of copyrights and patents (both in the United States and foreign countries) relating to Developments. I shall sign all papers, including, without limitation, copyright applications, patent applications, trademark or service mark applications, declarations, oaths, formal assignments, assignment of priority rights, and powers of attorney, which Parent may deem necessary or desirable in order to protect its rights and interests in any Development.

# 6. CURRENT EMPLOYMENT; NO CONTRARY AGREEMENTS.

I hereby represent that I am not bound by the terms of any agreement with any current or previous employer or other party to refrain from using or disclosing any trade secret or confidential or Proprietary Information in the course of my employment with Parent or to refrain from competing, directly or indirectly, with the business of such previous employer or any other party. I further represent that, and agree that, in the performance of my duties as a provider of services to Parent, I will not breach any agreement to keep in confidence Proprietary Information, knowledge or data acquired by me in confidence or in trust prior to my employment with Parent, and I will not disclose to Parent or induce Parent to use any confidential or proprietary information or material belonging to any previous employer or others. I represent and warrant to Parent that I am not now under any obligation of a contractual nature to any person, firm or corporation which is inconsistent or in conflict with this Agreement.

## 7. INJUNCTIVE RELIEF.

The restrictions contained herein are necessary for the protection of the business and goodwill of the Company, Parent and their affiliates and are considered by me to be reasonable for such purposes. I understand and agree that Parent will suffer irreparable harm in the event that I breach any of my obligations under this Agreement and that monetary damages will be inadequate to compensate Parent for such breach. Accordingly, I agree that, in the event of a breach or threatened breach by me of any of the provisions of this Agreement, Parent, in addition to and not in limitation of any other rights, remedies or damages available to Parent at law or in equity, shall be entitled to a permanent injunction in order to prevent or to restrain any such breach by me, or by my partners, agents, representatives, employers, employees and/or any and all persons directly or indirectly acting for or with me.

# 8. ACCOUNTING FOR PROFITS.

I covenant and agree that, if I shall violate any of my covenants or agreements under this Agreement, Parent, at its own expense, shall be entitled to an accounting and repayment of all profits, compensation, commissions, remunerations or benefits which I directly or indirectly have realized and/or may realize as a result of, growing out of or in connection with any such violation; such remedy shall be in addition to and not in limitation of any injunctive relief or other rights or remedies to which Parent is or may be entitled at law, in equity or under this Agreement.

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## 9. NO EMPLOYMENT CONTRACT.

I understand that this Agreement does not constitute a contract of employment and does not imply that my employment will continue for any period of time.

## 10. ENFORCEABILITY AND SCOPE.

In the event that any Section of this Agreement, or any provision of any such Section, shall for any reason be held to be wholly invalid, illegal or unenforceable, such invalidity, illegality, or unenforceability shall not affect any other Section hereof, or any other provision of an affected Section, and this Agreement shall be construed as if, and enforced as fully as if, such invalid, illegal or unenforceable Section or provision had never been contained herein. In the event any Section, or any provision thereof, is found to be partially invalid, illegal or unenforceable (on the ground, for example, that it is excessive in scope), then such Section or provision shall be enforced to the extent not invalid, illegal or unenforceable, and its partial invalidity, illegality or unenforceability shall not affect any other Section or provision of this Agreement. If any restriction set forth in Section 3 above is found by a court of competent jurisdiction to be unenforceable because it extends for too long a period of time, over too great a range of activities or in too broad a geographic area, such restriction shall be interpreted to extend only over the maximum period of time, maximum range of activities or maximum geographic area as to which it may be deemed to be enforceable.

#### 11. GENERAL.

(a) This Agreement supersedes all prior agreements, written or oral, between me and Parent relating to the subject matter of this Agreement, except for the the Change in Control Agreement and the Severance Agreement, which are referenced herein. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by me and Parent. I agree that any change or changes in my duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

(b) This Agreement will be binding upon my heirs, executors and administrators and will inure to the benefit of and be binding upon Parent and its successors and assigns.

(c) No delay or omission by Parent in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by Parent on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(d) I expressly consent to be bound by the provisions of this Agreement for the benefit of the Company, Parent or any of their affiliates to whose employ or other service providing arrangement I may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

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(e) Any notices required or permitted to be sent under this Agreement shall be effective when delivered by hand or mailed by registered or certified mail, return receipt requested, and addressed as follows:

If to Parent:

pSivida Limited Level 12, BGC Centre 28 The Esplanade, Perth WA 6000 Australia GPO Box 2535 Perth, WA 6831

With a copy to:

Curtis, Mallet-Prevost, Colt & Mosle LLP 101 Park Avenue New York, NY 10178 Attn: Lawrence Goodman, Esq.

If to Executive:

Paul Ashton 19 Brimmer Street Boston, MA 02108

Either party may change its address for receiving notices by giving notice to the other party.

(f) This Agreement is governed by and will be construed as a sealed instrument under and in accordance with the laws of the Commonwealth of Massachusetts.

I ACKNOWLEDGE AND UNDERSTAND THAT THIS AGREEMENT AFFECTS MY RIGHTS TO COMPETE WITH PARENT OR TO DISCLOSE AND USE PARENT'S PROPRIETARY INFORMATION OR DURING AND AFTER MY EMPLOYMENT.

I HAVE READ ALL OF THE PROVISIONS OF THIS AGREEMENT CAREFULLY AND I UNDERSTAND, AND AGREE TO, EACH OF SUCH PROVISIONS.

[SIGNATURE PAGE TO IMMEDIATELY FOLLOW]

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IN WITNESS WHEREOF, I have executed this Agreement under seal as of this 3 day of October, 2005.

/s/ Paul Ashton ------Paul Ashton

ACKNOWLEDGED AND AGREED:

PSIVIDA LIMITED

By: /s/ Gavin Rezos

Name: Gavin Rezos Title: Managing Director Stock Option Granted Under the 1997 Stock Option Plan

Stock Option granted by Control Delivery Systems, Inc., a Delaware corporation (the "Company"), to Paul Ashton (the "Optionee") pursuant to the Company's 1997 Stock Option Plan (the "Plan").

1. Grant of Option.

This certificate evidences the grant by the Company on September 18, 1997 to Optionee of an option to purchase, in whole or in part, on the terms herein provided, a total of 15,000 shares of common stock of the Company (the "Shares") at \$6.25 per Share, which is not less than the fair market value of the Shares on the date of grant of this option. This option must be exercised before 5:00 p.m., E.S.T. on September 18, 2007 ("Final Exercise Date").

This option is exercisable in the following installments prior to the Final Exercise Date:

up to 3,750 shares on and after September 18, 1998; up to an additional 3,750 shares on and after September 18, 1999; up to an additional 3,750 shares on and after September 18, 2000; and up to an additional 3,750 shares on and after September 18, 2001.

2. Exercise of Option.

Each election to exercise this option shall be in writing, signed by the Optionee or Optionee's executor or administrator or the person or persons to whom this option is transferred by will or the applicable laws of descent and distribution (the "Legal Representative"), and received by the Company at its principal office, accompanied by this certificate, and payment in full as provided in the Plan. The exercise price may be paid by delivery of cash, a certified check, bank draft or money order payable to the Company, common stock of the Company which have been outstanding at least six months and which have a fair market value equal to an unconditional and irrevocable undertaking by a broker to deliver promptly to the Company sufficient funds to pay the exercise price, or any combination of the foregoing. In the event that this option is exercised by the Optionee's Legal Representative, the Company shall be under no obligation to deliver Shares hereunder unless and until the Company is satisfied as to the authority of the person or persons exercising this option.

3. Notice of Disposition.

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The person exercising this option shall notify the Company when making any disposition of the Shares acquired upon exercise of this option, whether by sale, gift or otherwise.

4. Application of Stock Transfer Agreement.

If at the time this option is exercised the Company is a party to any agreement restricting the transfer of any outstanding shares of its Common Stock, this option may be exercised only if the Shares so acquired are made subject to the transfer restrictions set forth in that agreement (or if more than one such agreement is then in effect, the agreement specified by the Board of Directors of the Company).

5. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the person exercising this option shall have remitted to the Company an amount sufficient to satisfy any federal, state or local withholding tax requirements, or shall have made other arrangements satisfactory to the Company with respect to such taxes.

6. Nontransferability of Option.

This option is not transferable by the Optionee otherwise than by will or the laws of descent and distribution, and is exercisable during the Optionee's lifetime only by the Optionee.

7. Provisions of the Plan.

This option is subject to the provisions of the Plan, as amended from time to time, which shall be controlling in the event of any conflicting or inconsistent provisions. A copy of the Plan has been provided to the Optionee previously.

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

Control Delivery Systems, Inc.

By: /s/ Michael J. Soja

Dated: July 10, 2002

## Incentive Stock Option Granted Under the 1997 Stock Option Plan

Incentive Stock Option granted by Control Delivery Systems, Inc., a Delaware corporation (the "Company"), to Paul Ashton (the "Optionee") pursuant to the Company's 1997 Stock Option Plan (the "Plan").

## 1. Grant of Option

This certificate evidences the grant by the Company on August 26, 1999 to Optionee of an option to purchase, in whole or in part, on the terms herein provided, a total of 10,000 shares of common stock of the Company (the "Shares") at \$8.00 per Share, which is not less than [110%] of the fair market value of the Shares on the date of grant of this option. This option must be exercised before 5:00 p.m., E.S.T. on August 25, 2009 ("Final Exercise Date"). It is intended that the option evidenced by this certificate shall be an incentive stock option as defined in section 422 of the Internal Revenue Code of 1986, as amended from time to time, (the "Code").

This option is exercisable in the following installments prior to the Final Exercise Date:

up to 3,333 shares on and after August 26, 2000; up to an additional 3,333 shares on and after August 26, 2001; and up to an additional 3,334 shares on and after August 26, 2002.

## 2. Exercise of Option.

Each election to exercise this option shall be in writing, signed by the Optionee or Optionee's executor or administrator or the person or persons to whom this option is transferred by will or the applicable laws of descent and distribution (the "Legal Representative"), and received by the Company at its principal office, accompanied by this certificate, and payment in full as provided in the Plan. The exercise price may be paid by delivery of cash, a certified check, bank draft or money order payable to the Company, common stock of the Company which have been outstanding at least six months and which have a fair market value equal to an unconditional and irrevocable undertaking by a broker to deliver promptly to the Company sufficient funds to pay the exercise price, or any combination of the foregoing. In the event that this option is exercised by the Optionee's Legal Representative, the Company shall be under no obligation to deliver Shares hereunder unless and until the Company is satisfied as to the authority of the person or persons exercising this option.

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## 3. Notice of Disposition.

The person exercising this option shall notify the Company when making any disposition of the Shares acquired upon exercise of this option, whether by sale, gift or otherwise.

4. Application of Stock Transfer Agreement.

If at the time this option is exercised the Company is a party to any agreement restricting the transfer of any outstanding shares of its Common Stock, this option may be exercised only if the Shares so acquired are made subject to the transfer restrictions set forth in that agreement (or if more than one such agreement is then in effect, the agreement specified by the Board of Directors of the Company).

# 5. Withholding

No Shares will be issued pursuant to the exercise of this option unless and until the person exercising this option shall have remitted to the Company an amount sufficient to satisfy any federal, state or local withholding tax requirements, or shall have made other arrangements satisfactory to the Company with respect to such taxes.

6. Nontransferability of Option.

This option is not transferable by the Optionee otherwise than by will or the laws of descent and distribution, and is exercisable during the Optionee's lifetime only by the Optionee.

7. Provisions of the Plan.

This option is subject to the provisions of the Plan, as amended from time to time, which shall be controlling in the event of any conflicting or inconsistent provisions. A copy of the Plan has been provided to the Optionee previously.

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

Control Delivery Systems, Inc.

By /s/ ILLEGIBLE

Dated: July 10, 2002

ASHTON P. 8.26.99 -2-

Exhibit 8.1 to Annual Report on Form 20-F Of pSivida Limited

List of Subsidiaries

AION Diagnostics Limited, Australia pSiMedica Limited, United Kingdom pSiOncology Pte. Limited, Singapore pSivida Inc., United States EXHIBIT 12.1 CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS AMENDED.

#### CERTIFICATIONS

I, GAVIN REZOS, certify that:

1. I have reviewed this annual report on Form 20-F of PSIVIDA LIMITED;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238 and 34-47986];

(c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: JANUARY 18, 2006

/s/ GAVIN REZOS\*

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Gavin Rezos

CHIEF EXECUTIVE OFFICER AND MANAGING DIRECTOR

Title

#### CERTIFICATIONS

I, AARON FINLAY, certify that:

1. I have reviewed this annual report on Form 20-F of PSIVIDA LIMITED;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [Paragraph omitted pursuant to SEC release Nos. 33-8238 and 34-47986];

(c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: JANUARY 18, 2006

/s/ AARON FINLAY\*

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Aaron Finlay

### Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002.

In connection with the Annual Report of pSivida Limited (the "Company") on Form 20-F for the period ending June 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"). I, Gavin Rezos, Chief Executive Officer and Managing Director of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002, that: (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: JANUARY 18, 2006

/s/ Gavin Rezos\* - -----Gavin Rezos

## EXHIBIT 13.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002.

In the connection with the Annual Report of pSivida Limited (the "Company") on Form 20-F for the period ending June 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Aaron Finlay, Chief Financial Officer and Company Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that: (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: JANUARY 18, 2006

/s/ AARON FINLAY\*

CHIEF FINANCIAL OFFICER AND COMPANY SECRETARY

Title