UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

	FORM 1	10-Q
×	QUARTERLY REPORT PURSUANT TO SECTION 13 O 1934	R 15(d) OF THE SECURITIES EXCHANGE ACT OF
	For the quarterly period ended March 31, 2008	
	OR	
	TRANSITION REPORT PURSUANT TO SECTION 13 O	OR 15(d) OF THE SECURITIES EXCHANGE ACT OF
	For the transition period from to	
	COMMISSION FILE NU	JMBER 000-51122
	pSivida L (Exact name of registrant as sp	
	Western Australia, Commonwealth of Australia (State or other jurisdiction of incorporation or organization)	N/A (I.R.S. Employer Identification No.)
	Level 16 190 Queen Street Melbourne VIC 3000	
	Australia (Address of principal executive offices)	N/A (Zip Code)
	+61-8-9227- (Registrant's telephone numbe	
	Please send copies of notices and communications from	m the Securities and Exchange Commission to:
	Lori H. Freedm pSivida I 400 Pleasant Watertown, M	nc. Street
during	Indicate by check mark whether the registrant (1) has filed all reports required the preceding 12 months (or for such shorter period that the registrant was requents for the past 90 days. Yes No □	
	Indicate by check mark whether the registrant is a large accelerated filer, an ac initions of "large accelerated filer", "accelerated filer" and "smaller reporting	
	Large accelerated filer □ Accelerated filer 図 Non-ac	celerated filer Smaller reporting company
	Indicate by check mark whether the registrant is a shell company (as defined in	n Rule 12b-2 of the Exchange Act). YES □ NO 🗵
	730,518,7 (Number of issued and outstanding ord	

Certifications

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PSIVIDA LIMITED AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands except share amounts)

	March 31, 2008	June 30, 2007
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,175	\$ 2,670
Accounts and note receivable and other current assets	4,231	3,024
Total current assets	22,406	5,694
Property and equipment, net of accumulated depreciation of \$4,636 and \$4,631, respectively	308	512
Goodwill	55,386	55,496
Other intangibles, net of accumulated amortization of \$71,847 and \$69,010, respectively	37,766	40,802
Total assets	\$ 115,866	\$ 102,504
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,385	\$ 7,536
Deferred revenue	10,250	356
Derivative liabilities	2,262	8,865
Total current liabilities	15,897	16,757
Deferred revenue	10,191	1,346
Deferred tax liabilities	616	852
	26,704	18,955
Stockholders' equity:		
Common stock, no par value, 730,518,775 and 565,950,830 shares issued and outstanding, respectively	_	_
Additional paid-in capital	243,156	225,211
Accumulated deficit	(160,958)	(148,867)
Accumulated other comprehensive income	6,964	7,205
Total stockholders' equity	89,162	83,549
Total liabilities and stockholders' equity	\$ 115,866	\$ 102,504

PSIVIDA LIMITED AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands except per share amounts)

		Three Months Ended March 31,		ths Ended h 31,
	2008	2007	2008	2007
Revenues:	¢ 502	¢ 100	¢ (01	¢ 710
Collaborative research and development	\$ 503 39	\$ 102 267	\$ 681 92	\$ 712 771
Royalty income Total revenues				
	542	369	773	1,483
Operating expenses:	2.005	E 1E2	12.022	16.077
Research and development	3,605	5,153	12,022	16,877
Selling, general and administrative	3,546	2,064	8,609	8,272
Total operating expenses	7,151	7,217	20,631	25,149
Loss from operations	(6,609)	(6,848)	(19,858)	(23,666)
Other income (expense):				
Change in fair value of derivatives	1,172	(6,673)	7,193	(4,606)
Interest income	121	62	534	152
Interest and finance costs	(206)	(1,962)	(507)	(8,823)
Loss on extinguishment of debt	-	_	_	(12,147)
Other income, net	6	39	308	95
Total other income (expense)	1,093	(8,534)	7,528	(25,329)
Loss from continuing operations before income taxes	(5,516)	(15,382)	(12,330)	(48,995)
Income tax benefit	15	3,544	239	7,033
Loss from continuing operations	(5,501)	(11,838)	(12,091)	(41,962)
Loss from discontinued operations	_ ·	(359)		(1,294)
Net loss	\$ (5,501)	\$(12,197)	\$ (12,091)	\$ (43,256)
Basic and diluted net loss per share:				
Loss from continuing operations	\$ (0.01)	\$ (0.03)	\$ (0.02)	\$ (0.10)
Loss from discontinued operations	<u> </u>	_	_	_
Net loss	\$ (0.01)	\$ (0.03)	\$ (0.02)	\$ (0.11)
Weighted average ordinary shares outstanding:				
Basic and diluted	730,519	435,119	725,641	410,241

PSIVIDA LIMITED AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)

(In thousands, except share amounts)

	Common Stock		Additional		Accumulated Other	Total Stockholders' Equity	
	Number of Shares	Number of Par Value Pa		Accumulated Deficit	Comprehensive Income		
Balance at July 1, 2007	565,950,830	\$ —	\$225,211	\$ (148,867)	\$ 7,205	\$ 83,549	
Comprehensive loss:							
Net loss	_	_	_	(12,091)	_	(12,091)	
Foreign currency translation adjustments	_	_	_	_	(241)	(241)	
Total comprehensive loss						(12,332)	
Proceeds from issuance of stock, net of issue costs	164,567,945	_	18,387	_	_	18,387	
Stock-based compensation	_	_	148	_	_	148	
Proceeds allocated to derivative liabilities in connection with							
warrants issued to investors			(590)			(590)	
Balance at March 31, 2008	730,518,775	\$ —	\$243,156	\$ (160,958)	\$ 6,964	\$ 89,162	

PSIVIDA LIMITED AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Nine Months Ended March 31,	
	2008	2007
Cash flows from operating activities:	# (10 001)	# (4D D = 0)
Net loss	\$(12,091)	\$(43,256)
Adjustments to reconcile net loss to cash flows from operating activities:	222	4 ==0
Depreciation and amortization of property and equipment	320	1,578
Amortization of intangible assets	2,926	7,182
Amortization of convertible note debt discount and issue costs		4,680
Loss on extinguishment of debt		12,147
Non-cash interest expense	507	721
Change in fair value of derivatives	(7,193)	4,606
Stock-based compensation expense	148	672
Deferred income tax benefit	(239)	(7,033)
Changes in operating assets and liabilities:	(4.004)	(446)
Accounts and note receivable and other current assets	(1,201)	(446)
Accounts payable and accrued expenses	(4,655)	1,327
Deferred revenue	18,775	162
Cash flows used in operating activities	(2,703)	(17,660)
Cash flows from investing activities:		
Purchases of property and equipment	(133)	(71)
Cash flows used in investing activities	(133)	(71)
Cash flows from financing activities		
Proceeds from issuance of stock	20,622	12,016
Stock issuance costs	(2,235)	(739)
Proceeds from issuance of convertible notes	_	6,500
Debt issuance costs	_	(1,787)
Repayment of convertible notes	_	(2,500)
Premium paid on extinguishment of debt	_	(1,000)
Cash flows provided by financing activities	18,387	12,490
Effect of foreign exchange rate changes on cash and cash equivalents	(46)	(92)
Net change in cash and cash equivalents	15,505	(5,333)
Cash and cash equivalents at beginning of period	2,670	11,278
Cash and cash equivalents at end of period	\$ 18,175	\$ 5,945

pSivida Limited and Subsidiaries

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Basis of Presentation

pSivida Limited (together with its subsidiaries, the "Company", "we" or "us") is incorporated in Western Australia and is a global drug delivery company committed to the biomedical sector and the development of therapeutic delivery products.

Following the closing of its stock offering (see Note 3) in July 2007, the Company no longer qualified as a foreign private issuer and, as a result, was required, commencing with the first quarter of the fiscal year ending June 30, 2008, to comply with all of the reporting requirements of the Securities Exchange Act of 1934, as amended, and other rules applicable to a United States domestic issuer. Further, the Company was required to file reports containing financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and presented in U.S. dollars.

Accordingly, effective for the quarter ended September 30, 2007, the Company changed its primary basis of accounting from Australian equivalents to International Financial Reporting Standards ("A-IFRS") to U.S. GAAP. The accompanying condensed consolidated financial statements as of March 31, 2008 and June 30, 2007 and for the three and nine months ended March 31, 2008 and 2007 are unaudited and have been prepared in accordance with U.S. GAAP and applicable regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Certain information and footnote disclosures normally included in U.S. GAAP financial statements have been condensed or omitted pursuant to such rules and regulations.

The unaudited condensed consolidated financial statements included herein should be read in conjunction with the Company's audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 20-F for the year ended June 30, 2007 filed with the SEC. The consolidated financial statements included in the Company's Form 20-F are presented in Australian dollars in accordance with A-IFRS and include a reconciliation to U.S. GAAP in Note 28 thereto. In the opinion of management, except for the change to the US\$ reporting currency, these unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements reconciled to U.S. GAAP as of and for the year ended June 30, 2007, and include all adjustments of a normal and recurring nature that are necessary to present fairly the consolidated financial position, results of operations and cash flows of the Company for the interim periods. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year.

These unaudited condensed consolidated financial statements have been presented in U.S. dollars. Throughout this quarterly report on Form 10-Q, references to "US\$" and "\$" are to U.S. dollars and references to A\$ are to Australian dollars.

Business Risks and Uncertainties

The Company's prospects are subject to the risks and uncertainties typical of companies that have achieved limited commercialization of their products and technologies. These risks include, but are not limited to, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials, dependence on third party collaborators, need for regulatory approval of products, successful protection of intellectual property, competition with larger, better-capitalized companies and possible dependence on key individuals. As a result, the Company's operating results may fluctuate significantly in the future.

The success of the Company's technology and business development programs and, ultimately, the attainment of profitable operations, is dependent on future events, including the Company's ability to continue its development activities and ultimately to achieve revenues in excess of its costs and expenses. The Company cannot be certain that it will be able to maintain its existing collaboration agreements, achieve additional collaboration agreements or obtain other sources of funding, if and when needed, on acceptable terms, if at all, or that the Company will be able to achieve revenues sufficient for profitable operations. If the Company is unable to do so, it could be required to reduce the scope of its development plans and operations.

Going Concern Basis

In its Report on Form 10-Q for the three months ended December 31, 2007, the Company disclosed that it had limited sources

of ongoing revenues and that it would need to raise additional cash through (a) non-dilutive collaboration development partnerships and/or (b) sales of equity and/or debt capital in future periods. The Company's unaudited condensed consolidated financial statements at December 31, 2007 and for the three and six month periods then ended were prepared on a going concern basis of accounting, which contemplated the continuity of normal business activity, realization of assets and settlement of liabilities in the normal course of business. Although the Company believed at that time that the basis upon which those financial statements were prepared was appropriate under the circumstances, the Company also believed that if the Company was unable to raise additional capital from time to time as required there would be substantial doubt as to the ability of the Company to continue as a going concern.

As a result of cash consideration received by the Company pursuant to the March 14, 2008 amendment of its license and collaboration agreement with Alimera Sciences, Inc. ("Alimera"), as further discussed in Note 4, the Company currently believes that its cash and cash equivalents at March 31, 2008, together with expected payments and funding of research and development in connection with the Company's agreements with Alimera and Pfizer, Inc. ("Pfizer"), will be sufficient to fund the Company's operations under its current operating plan through at least June 30, 2010. Accordingly, the Company does not believe that it will be required to raise additional cash within the next year to continue as a going concern.

2. Significant Accounting Policies

Principles of Consolidation

The unaudited condensed consolidated financial statements include the accounts of pSivida Limited and its wholly owned subsidiaries. Intercompany balances and transactions have been eliminated in consolidation.

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions and estimates that affect (i) reported amounts of assets and liabilities; (ii) disclosure of contingent assets and liabilities at the date of the consolidated financial statements; and (iii) reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates, and such differences could be material to the accompanying condensed consolidated financial statements.

Foreign currency translation

Functional currency

Upon the acquisition of pSivida Inc. (formerly Control Delivery Systems Inc ("CDS") in December 2005, the parent company determined that the United States was the primary economic environment in which it operated. Accordingly, effective January 1, 2006, the parent company changed its functional currency from A\$ to US\$. The functional currency of each other entity is the currency of the primary economic environment in which that entity operates, primarily the U.S. dollar or the Pound Sterling.

Foreign currency transactions

In preparing the financial statements of the individual entities, transactions denominated in currencies other than the entity's functional currency ("foreign currencies") are recorded at the rate of exchange prevailing on the dates of the transactions. At each balance sheet date, monetary items denominated in foreign currencies are translated at the exchange rate prevailing at that date. Gains and losses arising from transactions denominated in foreign currencies are included in other income, net in the consolidated financial statements.

Foreign operations

On consolidation, the assets and liabilities of the entities whose functional currency differs from the Company's US\$ reporting currency are translated at exchange rates prevailing at the reporting date. Income and expense items are translated at the average exchange rates for the period. Exchange differences are included in stockholders' equity as a component of accumulated other comprehensive income and are recognized in the consolidated statement of operations on disposal of the foreign operation.

Cash and cash equivalents

Cash consists of demand deposits. Cash equivalents are highly liquid investments with maturities of less than three months at the date of acquisition that are readily convertible to known amounts of cash.

Fair value of financial instruments

The carrying amounts of the Company's cash and cash equivalents, accounts and note receivable, accounts payable and accrued expenses approximate fair values because of their short-term maturity.

Debt and equity instruments

Debt and equity instruments are classified as either liabilities or equity in accordance with the substance of the contractual arrangement. Warrants and options issued in connection with share issues that are denominated in a currency (A\$) other than the issuer's functional currency (US\$) are treated as a derivative liability, reflecting the variable amount of functional currency to be received upon potential exercise. After initial recognition, subsequent changes in the fair value of the derivative liability are recorded in the consolidated statement of operations in each reporting period. Fair value is determined using a Black-Scholes valuation model.

Convertible notes

The proceeds received upon the issuance of a convertible note with detachable warrants are allocated into liability and equity components on a relative fair value basis. Management reviews the terms of a compound instrument to determine whether there are embedded derivatives that may be required to be bifurcated and accounted for separately as a derivative financial instrument. In connection with the Company's issuance of convertible notes during the years ended June 30, 2007 and 2006, management determined that the noteholder conversion options were required to be bifurcated and accounted for separately as derivative financial instruments. Bifurcated embedded derivatives are initially recorded at fair value as a reduction of the liability component of the convertible debt instrument. Changes in the fair value of the embedded derivative are recorded in the consolidated statement of operations in each subsequent reporting period. Fair value is estimated using a Binomial Tree Model. At March 31, 2008 and June 30, 2007, the Company had no embedded derivative liabilities that required bifurcation as its convertible notes were redeemed in full prior to June 30, 2007.

Amendments of convertible note transactions are accounted for as debt extinguishments or modifications based upon an assessment of the future cash flows of the amended note, including cash and non-cash consideration, compared to the future cash flows of the original note. The respective future cash flows are discounted using the imputed interest rate determined for the original note transaction. If the resulting present values reflect a change of greater than 10%, the transaction is accounted for as an extinguishment of debt and the issuance of a new convertible debt instrument. Alternatively, if the resulting present values reflect a change of less than 10%, the amendment is treated as a modification of the original debt instrument. Debt issue costs paid to third parties in connection with an amendment accounted for as an extinguishment are treated as a deferred cost, subject to amortization, whereas debt issue costs related to a debt modification are expensed as a period cost. During the nine months ended March 31, 2007, the Company entered into three amendments of a convertible note previously issued on November 16, 2005 to Sandell Asset Management ("Sandell"), two of which were accounted for as debt extinguishments (see Note 6) and one of which was accounted for as a debt modification.

Property and equipment

Property and equipment is stated at cost. The Company provides for depreciation and amortization using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the remaining lease term or the useful life of the asset. Property and equipment is depreciated over three years.

Repair and maintenance costs are expensed as incurred.

Leases

Leases are classified at their inception as either operating or capital leases based on the economic substance of the agreement. Lease payments made under operating leases are recognized as an expense on a straight-line basis over the lease term. Contingent rentals are recognized as an expense in the financial year in which they are incurred.

Acquired goodwill and intangible assets

The Company determines the estimated fair values of acquired intangible assets with definitive lives based on valuations performed by the Company at the time of their acquisition in accordance with Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations" ("SFAS 141").

Goodwill acquired in a business combination is initially measured as the excess of the cost of the business combination over the

acquirer's interest in the net fair value of the identifiable assets, liabilities and contingent liabilities recognized in accordance with SFAS 141. All potential intangible assets acquired in a business combination are identified and recognized separately from goodwill where they satisfy the definition of an intangible asset and their fair value can be measured reliably. The Company amortizes its intangible assets on a straight-line basis over their estimated useful lives. In-process research and development ("IPR&D") projects acquired in a business combination are recognized in the acquisition balance sheet and immediately expensed if the technological feasibility of the IPR&D has not yet been established and it has no alternative future use. The Company evaluates goodwill for impairment annually as of June 30 and whenever events or changes in circumstances ("triggering events") indicate that the carrying value may no longer be recoverable.

Impairment of long-lived assets

The Company evaluates long-lived assets, including intangible assets with definite lives, for impairment whenever triggering events indicate that the carrying value of an asset may no longer be recoverable. An evaluation of recoverability is performed by comparing the carrying values of the assets to projected future cash flows, in addition to other quantitative and qualitative analyses. If the carrying value of an asset exceeds its expected future pre-tax undiscounted cash flows, the Company will write down the carrying value of the intangible asset to its fair value in the period identified. The Company calculates fair value as the present value of estimated future cash flows to be generated by the asset using a risk-adjusted discount rate.

At June 30, 2007, the Company identified triggering events in connection with its Retisert® intangible asset. The analysis of its recoverable amount resulted in an impairment write-down of \$45,278,000 at June 30, 2007. There were no impairment write-downs associated with our long-lived assets during the three and nine months ended March 31, 2008 and 2007.

Amortization of intangible assets totaled \$962,000 and \$2,926,000 during the three and nine months ended March 31, 2008, respectively and \$2,032,000 and \$7,182,000 during the three and nine months ended March 31, 2007, respectively. The carrying value of intangible assets at March 31, 2008 of \$37,766,000 will be amortized on a straight-line basis over the remaining estimated useful life of 9.75 years.

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. The following specific recognition criteria must also be met before revenue is recognized:

Royalties

Royalty revenue is recognized on an accrual basis and consists of amounts earned from licensees as a designated percentage of their sales of products utilizing the Company's licensed technologies and are generally paid on a quarterly basis. Non-refundable royalties received in advance for which the Company has no obligation to perform future services are recognized when received. In connection with the Retisert product, CDS and Bausch & Lomb Incorporated ("Bausch & Lomb") entered into an advance royalty agreement in June 2005 pursuant to which Bausch & Lomb was entitled to retain (i) 50% of the first \$3.0 million of royalties otherwise payable and (ii) 100% of the next \$4.75 million of royalties otherwise payable under their license agreement. As of March 31, 2008, the next \$3.3 million of royalties otherwise payable to the Company will be retained by Bausch & Lomb.

Collaborative research and development

The Company's business strategy includes entering into collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing the Company's technologies. The terms of these agreements typically include multiple deliverables by the Company (for example, license rights, providing research and development services and manufacturing of clinical materials) in exchange for consideration to the Company of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development milestones and royalties in the form of a designated percentage of product sales or profits. The Company follows the provisions of the SEC's Staff Accounting Bulletin ("SAB") No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements", as amended by SAB No. 104 ("SAB 104"), "Revenue Recognition", and Emerging Issues Task Force ("EITF") Issue No. 00-21 ("EITF 00-21"), "Accounting for Revenue Arrangements with Multiple Deliverables". With the exception of royalties, these types of consideration are classified in the Company's statement of operations as collaborative research and development when revenue recognition is appropriate.

Non-refundable license fees are recognized as revenue when the Company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured and the Company has no further performance obligations under the license agreement. Multiple element arrangements, such as license and development arrangements,

are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting in accordance with EITF 00-21. The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting.

For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, are recognized as revenue on a straight-line basis over the period the Company expects to complete its performance obligations. The cumulative amount of revenue earned is limited to the cumulative amount of payments received as of the period ending date.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance. Deferred revenue amounts are classified as current liabilities to the extent that revenue is expected to be recognized within one year.

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

Research and development costs

Research and development costs are recognized as an expense in the period in which they are incurred. Research and development costs include wages, benefits and other operational costs related to the Company's research and development departments, clinical trial activities and supplies and amortization of intangible assets.

Stock-based compensation

Effective July 1, 2005, the Company adopted SFAS No. 123(R), "Share-Based Payment" ("SFAS 123(R)"), which requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their fair values. SFAS 123(R) is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), and supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", and its related implementation guidance. The Company elected the "modified prospective" method of applying SFAS 123(R) pursuant to which restatement of prior period results was not required. Under this method, compensation expense is recognized beginning with the adoption date (i) based on the requirements of SFAS 123(R) for all share-based payments granted after the adoption date and (ii) based on the requirements of SFAS 123 for all awards granted to employees prior to the adoption date of SFAS 123(R) that were unvested at the adoption date. SFAS 123(R) requires the Company to apply an estimated forfeiture rate when calculating the expense for the period, whereas SFAS 123 permitted the recording of forfeitures on an actual basis.

In connection with the December 2005 acquisition of CDS, the Company issued stock awards in the form of American Depositary Shares ("ADSs") (one ADS is equal to ten ordinary shares) to CDS employees in exchange for their restricted CDS stock. Deferred compensation related to these non-vested ADSs is charged to compensation expense over the remaining requisite service period.

The Company granted 5,450,000 options pursuant to its Employee Share Option Plan (the "Plan") during the nine months ended March 31, 2008. No options were exercised during the nine months ended March 31, 2008. The exercise prices of all outstanding options at March 31, 2008 were in excess of the market price of the Company's shares at that date and, accordingly, the options had no intrinsic value.

The Company uses the Black-Scholes option pricing model to calculate the fair value of stock option grants. The key assumptions for this valuation method include the expected life of the option, stock price volatility, the risk-free interest rate and dividend yield. Many of these assumptions are judgmental and highly sensitive in the determination of fair value. The expected life is based upon limited historical exercise behavior adjusted for subjective factors that may influence future exercise patterns, including the shift in operational focus during the past two years to the U.S. The Company uses an expected stock-price volatility assumption that is a combination of historical and current implied volatilities of the underlying stock which is obtained from public data sources. The risk-free interest rate is based upon published government bond rates over a term equivalent to the expected option term. An assumed dividend yield of zero reflects the fact that the Company has never paid cash dividends and has no intentions to pay dividends in the foreseeable future.

For option grants to non-executives, an estimated forfeiture rate of 10% has been used in calculating stock-based compensation. No forfeiture rate has been used for option grants to executive officers and directors. Additional expense will be recorded if the actual forfeiture rate is lower than estimated, and a recovery of prior year expense will be recorded if the actual forfeiture rate is higher than estimated.

The key weighted average assumptions used in the option valuation calculations for options granted under the Plan are as follows:

	Nine Month March	
	2008	2007
Option life (in years)	4.61	2007 4.49
Stock volatility	70.0%	65.0%
Risk-free interest rate	6.39%	5.89%
Expected dividends	_	_

No options were granted under the Plan during the three months ended March 31, 2008 and 2007. The weighted average grant date fair value of stock options granted pursuant to the Plan during the nine months ended March 31, 2008 and 2007 was A\$0.06 and A\$0.16, respectively.

A reconciliation of stock option activity pursuant to the Plan for the nine months ended March 31, 2008 is summarized as follows:

	Number of Ordinary Share Options	Weighted Average Exercise Price A\$	Remaining Contractual <u>Life</u> (in years)
Outstanding at June 30, 2007	18,673,504	0.95	
Granted	5,450,000	0.14	
Exercised	_	_	
Cancelled	(5,904,393)	0.72	
Outstanding at March 31, 2008	18,219,111	0.74	2.64
Exercisable at March 31, 2008	11,314,943	1.04	1.70

Stock-based compensation expense, including amortization of non-vested ADSs, is classified in the consolidated statements of operations for the three and nine months ended March 31, 2008 and 2007 as follows:

	Three Months Ended March 31,			Nine Months Ended M			March 31,		
	2008		2008 200		2007		2008		2007
		(In th	ousands)			(In the	usands)		
Research and development	\$	4	\$	64	\$	26	\$	501	
Selling, general and administrative		58		(209)		122		155	
Loss from discontinued operations			_	_			16		
	\$	62	\$	(145)	\$	148	\$	672	

As of March 31, 2008, there was \$277,000 of unrecognized compensation expense related to non-vested stock-based payment awards that is expected to be recognized over a weighted average period of approximately 1.6 years.

Net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted average number of ordinary shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the sum of (i) the weighted average number of ordinary shares outstanding and (ii) the weighted average number of ordinary shares that would be issued on the conversion of all dilutive securities outstanding. Potentially dilutive shares of 466,269,073 and 380,581,015 outstanding at March 31, 2008 and 2007 were not included in the calculation of diluted net loss per share for the three and nine months ended March 31, 2008 and 2007, respectively, as their inclusion would be anti-dilutive.

Potentially dilutive shares at March 31, 2008 and 2007 are summarized as follows:

	March 31,	
	2008	2007
	(in ordinary sha	re equivalents)
Plan options over ordinary shares	18,219,111	18,993,504
Other options over ADSs	762,720	1,576,500
Investor warrants over ordinary shares	159,467,332	130,799,801
Investor warrants over ADSs	287,819,910	113,918,040
Convertible notes		115,293,170
	466,269,073	380,581,015

Income tax

The Company accounts for income taxes using an asset and liability approach. The Company computes deferred income tax assets and liabilities for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. The Company will establish valuation allowances when necessary to reduce deferred tax assets to the amount that more likely than not will be realized.

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

3. Stockholders' Equity

The Company has historically financed its operations primarily through the sale of equity securities.

Share Offering

In July 2007, the Company completed a sale of 14,402,000 units at a price of \$1.25 per unit for gross proceeds of \$18,002,000. Each unit consisted of (i) one ADS, representing ten ordinary shares; and (ii) one warrant to purchase 0.40 ADS, with a warrant exercise price of \$1.65 per ADS. Of the total, 5,200,000 units were purchased by Pfizer in accordance with the terms of the Collaborative Research and License Agreement dated April 3, 2007. An additional 288,040 warrants to purchase ADSs were issued to the placement agents with a warrant exercise price of \$1.65. The fair value of warrants was deducted from the related proceeds of the sale of shares as a share issue cost. In addition, the Company simultaneously completed a sale of ordinary shares and warrants to an Australian investor at the equivalent price of A\$0.146 (\$0.125) per unit. Each unit consisted of (i) one ordinary share; and (ii) one warrant to purchase 0.40 ordinary share, with a warrant exercise price of A\$0.192 (\$0.165) per ordinary share. This sale of 20,547,945 units resulted in additional gross proceeds of A\$3,000,000 (\$2,620,000). Aggregate share issue costs in respect of the July 2007 sales totaled \$2,235,000, resulting in total net proceeds of \$18,387,000.

Investor Warrants to Purchase ADSs and Common Shares

Investor warrants include warrants and options issued to investors as part of, or in connection with, the Company's various debt and equity financing transactions. Investor warrants exclude all options issued under the Plan, as well as options to purchase ADSs issued in connection with the CDS acquisition.

At March 31, 2008, the Company had outstanding the following US\$-denominated investor warrants to purchase ADSs with a weighted average remaining life at March 31, 2008 of 3.9 years:

		Nine Months Ended March 31,				
	200	8	2007			
		Weighted Average		Weighted Average		
	Number of		Number of	Exercise		
	Warrants over ADSs	Price US\$	Warrants over ADSs	Price US\$		
Outstanding at beginning of period	22,733,151	2.00	766,803	8.12		
Granted	6,048,840	1.65	10,625,001	1.89		
Outstanding and exercisable at end of period	28,781,991	1.92	11,391,804	2.31		

At March 31, 2008, the Company had outstanding the following A\$-denominated investor warrants to purchase ordinary shares with a weighted average remaining life at March 31, 2008 of 2.9 years:

		Nine Months Ended March 31,				
	2008		2007			
	Number of Warrants Over Ordinary Shares	Weighted Average Exercise Price A\$	Number of Warrants Over Ordinary Shares	Weighted Average Exercise Price A\$		
Outstanding at beginning of period	151,248,154	0.25	2,050,000	1.09		
Granted	8,219,178	0.19	128,749,801	0.24		
Outstanding and exercisable at end of period	159,467,332	0.25	130,799,801	0.25		

4. Amended and Restated Collaboration Agreement

On March 14, 2008, the Company and Alimera amended and restated their license and collaboration agreement dated February 11, 2005 relating to Medidur™ FA, the companies' Phase III investigative treatment for diabetic macular edema ("DME"), and certain other products. In exchange for current and future consideration to the Company of up to approximately \$78 million, the Company decreased its share in the future profits of Medidur FA from 50% to 20%.

Current consideration consisted of (i) \$12.0 million in cash paid upon the execution of the amended collaboration agreement and (ii) cancellation of \$5.7 million of accrued development cost liabilities, including related penalties and accrued interest, owed by the Company to Alimera as of March 14, 2008. The Company's performance period under the Alimera Amendment ends December 31, 2009. Accordingly, as of the effective date, the aggregate \$18.3 million of deferred revenue, consisting of the aforementioned current consideration and an additional \$650,000 of previously received but unamortized milestone payments, will be recognized as revenue on a straight-line basis over the 21.5 month performance period through December 31, 2009.

Other consideration, exclusive of the Company's 20% profit share, includes (i) conditional principal and interest payments of up to approximately \$21.0 million through September 2012 under a note issued by Alimera; (ii) a \$25.0 million milestone payment upon Food and Drug Association ("FDA") approval of Medidur FA for DME and (iii) reimbursement of budgeted or approved development costs actually incurred by the Company. All future payments received from Alimera during the performance period will be recognized as revenue during the performance period using the cumulative catch-up method. All payments received after December 31, 2009 will be recognized as revenue when earned.

In addition, the assumption by Alimera of all financial responsibility for the development of licensed products under the

collaboration agreement will result in the elimination of an estimated \$14.0 million of future development cost obligations that would otherwise have been payable by the Company to Alimera pursuant to the terms of the original collaboration agreement.

5. License Agreement and Related Sale of Assets

On January 17, 2008, the Company and Intrinsiq Materials Cayman Limited ("Intrinsiq") entered into an agreement pursuant to which Intrinsiq acquired an exclusive license to develop and commercialize nutraceutical and food science applications of BioSilicon, and certain related assets, for \$1,230,000. Intrinsiq paid \$500,000 at closing and agreed to make additional payments totaling \$730,000 through January 2009. In addition, subject to its unilateral right to terminate the license upon 90 days prior written notice, Intrinsiq will be obligated to pay the Company minimum royalties of \$3.95 million over six years, of which the first \$500,000 payment is due 18 months after the closing.

The Company is required to spend approximately \$460,000 to expand the Company's BioSilicon manufacturing capacity and is obligated to enter into a supply agreement with Intrinsiq. As of March 31, 2008, the Company has incurred approximately \$125,000 of the expansion costs, which have been recorded as property and equipment, subject to depreciation once the assets are placed in service.

The license and future supply agreements have been combined as a single unit of accounting in accordance with the provisions of EITF 00-21. Until such time as the supply agreement is consummated and evaluated under EITF 00-21, the Company is unable to determine the term of its performance obligations under the license agreement. Accordingly, the contractual license fees, net of the net book value of assets disposed, have been classified as deferred revenue and will not be subject to revenue recognition until the Company can determine the performance period.

6. Loss on Extinguishment of Debt

On September 14, 2006, the Company amended the terms of the convertible note issued to Sandell on November 16, 2005 (the "amended note"). The amended note continued to have a three-year term and to bear 8% interest payable quarterly in arrears in cash or, under certain conditions, at our option, in the form of ADSs. The conversion price was adjusted to \$2.00 per ADS, subject to further adjustment based upon certain events or circumstances, including, without limitation, if 108% of the average market price of our ADSs for the ten trading days prior to April 30, 2007 was lower than the then current conversion price. Sandell's conditional redemption rights under the original note were replaced by unilateral redemption rights for up to 50% of the amended note principal at each of July 31, 2007 and January 31, 2008. In connection with the amendment, the Company repaid \$2.5 million of the outstanding note principal and agreed to pay \$1.0 million in related fees, which were paid on September 14, 2006. Furthermore, as part of the amended note, Sandell extended the deadline for the registration statement required by the registration rights agreement to be declared effective by the SEC through October 15, 2006, with increased penalties if that deadline were missed. The registration statement was declared effective on September 29, 2006. The Company also granted to Sandell (i) Series A warrants to purchase 5.7 million ADSs exercisable for five years with an exercise price of \$1.80 per ADS; (ii) a security interest in current royalties, subject to release upon any disposition of the royalty stream; and (iii) a guarantee by its US subsidiary, pSivida Inc.

The present value of the future cash flows of the amended note, including the \$1.0 million of cash fees paid and the \$8.7 million value of the Series A warrants granted, was determined to be substantially different compared to the future cash flows under the original note terms, both discounted using the effective interest rate determined under the original note. As a result, the Company recorded a loss on extinguishment of debt of \$8,871,000, which represented the difference between the carrying amount of the original debt instrument and the consideration paid, including the value of the Series A warrants. The amended note, embedded conversion option derivative and the Series A warrants were valued using a Binomial Tree Model.

On October 17, 2006, the Company signed a letter agreement with Sandell further revising the terms of the amended note. Pursuant to that letter agreement, the requirement to maintain a net cash balance in excess of 30% of the outstanding principal amount of the amended note was waived until March 30, 2007 and instead the net cash balance required to be held through that date was reduced to \$1.5 million. Sandell further waived any default that would otherwise have resulted from the unavailability of our resale prospectus until the filing with the SEC of our 2006 audited financial statements reconciled to U.S. GAAP. The Company filed those financial statements on October 31, 2006, thus satisfying the condition in the agreement. In exchange for the foregoing, the Company agreed to make (i) a one-time payment to Sandell of \$800,000 on December 28, 2006 in satisfaction of registration rights penalties through the date of the letter agreement; and (ii) three payments of \$150,000 on January 31, 2007, February 28, 2007 and March 30, 2007.

The present value of the future cash flows of the amended note, as further modified, was determined not to be substantially different compared to the future cash flows of the original amended note, both discounted using the effective interest rate as determined under the amended note dated September 14, 2006. Accordingly, the \$450,000 of cash fees and the transaction costs directly related to the letter agreement reduced the carrying amount of the amended note, subject to amortization over the remaining term at an adjusted effective interest rate.

On December 29, 2006, we entered into a second amendment agreement with Sandell revising the amended note (the "second amended note"), pursuant to which Sandell agreed, subject to closing, to a general forbearance with respect to any defaults through March 31, 2007 or such earlier date as defined in the second amendment agreement, including the following:

- Sandell agreed to allow us to transfer or grant security interests in certain of our assets which would be necessary if we were to complete a then potential transaction;
- Sandell agreed to forego the cash interest payment due on January 2, 2007 in favor of adding approximately \$306,000 to the outstanding principal amount of the convertible note, which amount represented the value of the ADSs which we would have issued to satisfy the payment had we met certain conditions allowing us to pay the interest with ADSs;
- Sandell agreed to defer our scheduled payment of \$800,000;
- Sandell agreed to forgive \$770,000 of pending registration delay penalties;
- Sandell agreed to amend the debt covenants to release us from the obligation to satisfy a minimum cash balance test of 30% of the outstanding note principal; and
- Sandell agreed that we would have until ten days after March 31, 2007, or such earlier date as defined in the second amendment agreement, to file a registration statement with respect to securities issuable on exercise of Sandell's Series A warrants.

In return for the foregoing, we issued to Sandell Series C warrants to purchase 1.5 million ADSs over five years with an exercise price of \$2.00 per ADS and agreed, upon receipt of required approvals, including shareholder approval, and satisfaction of other closing conditions, to issue additional Series D warrants to purchase 4.0 million ADSs over five years with an exercise price of \$2.00 per ADS.

The present value of the future cash flows of the second amended note, including the value of the Series C warrants issued, was determined to be substantially different compared to the future cash flows of the amended note, both discounted using the effective interest rate as determined under the original amended note. We recorded a loss on extinguishment of debt of \$3,276,000, which represented the difference between the carrying amount of the amended note instrument and the consideration paid, including the value of the Series C warrants.

In May 2007, the Company paid the Sandell convertible note in full.

7. Derivative liabilities

The following table provides a reconciliation of derivative liabilities for the nine months ended March 31, 2008 and the year ended June 30, 2007:

	Nine Months Ended March 31, 2008 (In thousands)			ear Ended ne 30, 2007
Balance—beginning of period	\$	8,865	\$	1,800
In connection with warrants issued to investors (i)		590		15,632
In connection with issuance of and amendments to convertible notes (ii)		_		14,867
Write-off in connection with loss on extinguishment of debt (ii)		_		(12,000)
Decrease in fair value of derivatives		(7,193)		(11,434)
Balance—end of period	\$	2,262	\$	8,865

- (i) In connection with capital raising transactions during the year ended June 30, 2007, the Company issued ordinary shares together with detachable warrants (exercisable over four years) that were denominated in A\$, which is different than the Company's US\$ functional currency. To the extent that the potential exercise of these warrants would result in a variable amount of proceeds in the issuer's functional currency the fair value of the warrants issued was recorded as a derivative liability, with a corresponding reduction in share capital, subject to revaluation of the liability on a marked to market basis through the consolidated statements of operations.
 - In connection with a capital raising transaction in July 2007, the Company issued ordinary shares and ADSs together with detachable warrants (exercisable over five years) denominated in A\$ and US\$, respectively. The fair value of the A\$-denominated warrants was recorded as a derivative liability, with a corresponding reduction in share capital, subject to periodic revaluations of the liability on a marked to market basis through the consolidated statements of operations.
 - At March 31, 2008 and June 30, 2007, the fair values of these derivative liabilities totalled \$2,262,000 and \$8,865,000, respectively. The net change in the fair value of these derivative liabilities during the three and nine months ended March 31, 2008 resulted in income recognized of \$1,172,000 and \$7,193,000, respectively, and during each of the three and nine month periods ended March 31, 2007 resulted in expense of \$2,173,000.
- (ii) The conversion option derivative liabilities arose in connection with the issuance and amendments of the Sandell subordinated convertible note described above and in connection with the issuance of subordinated convertible notes to certain institutional investors (hereinafter referred to as "Absolute") in September 2006. The terms of these notes created hybrid financial instruments that consisted of a loan host contract and a compound embedded derivative. The net increase in the fair value of these derivative liabilities during the three and nine months ended March 31, 2007 resulted in expense recognized of \$4,500,000 and \$2,433,000 respectively. The fair values of the conversion option derivative immediately prior to the September 14, 2006 and December 29, 2006 amendments of the Sandell convertible note, each in the amount of \$4,000,000 were written off through the consolidated statements of operations as part of the calculation of the loss on extinguishment of debt (see Note 6).

8. Income Tax

Deferred income tax benefit for the three and nine months ended March 31, 2008 was \$15,000 and \$239,000, respectively. This compares to deferred income tax benefit of \$3.5 million and \$7.0 million, respectively, for the three and nine months ended March 31, 2007. The recorded tax benefit in the Company's consolidated financial statements differs from the amount calculated using the U.S. statutory corporate tax rate of 34%. This difference is primarily attributable to valuation allowances that the Company records against its deferred tax assets, primarily related to tax loss carryforwards as well as income or losses in jurisdictions with different tax rates. The valuation allowances are recorded since there is no evidence that the Company will have sufficient taxable income to utilize a portion of its tax loss carryforwards.

In July 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). FIN 48 prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise's financial statements in accordance with SFAS No. 109, "Accounting for Income Taxes". Tax positions must meet a more-likely-than-not recognition threshold at the effective date to be recognized upon the adoption of FIN 48 and in subsequent periods. The Company has adopted FIN 48 as of July 1, 2007. The adoption of FIN 48 did not have a material impact on the Company's unaudited condensed consolidated financial statements. As of the adoption date and as of March 31, 2008, the Company had no significant unrecognized tax benefits other than tax losses not recognized in the accompanying unaudited condensed consolidated financial statements.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of March 31, 2008, the Company had no accrued penalties or interest related to uncertain tax positions.

The Company and all of its subsidiaries have incurred operating losses since inception. The entities within the consolidated group had net operating loss ("NOL") carryforwards in various tax jurisdictions at March 31, 2008. The Company's U.S. Federal tax returns for calendar years 2004 through 2007 remain subject to examination by the Internal Revenue Service. The Company's U.K. tax returns for the years ended June 30, 2006 and 2007 remain subject to examination. The Company's Australian tax returns for the years ended June 30, 2004, 2005, 2006 and 2007 remain subject to examination.

As of March 31, 2008 the Company has recorded a valuation allowance of \$24.8 million against deferred tax assets related to these NOL carryforwards since there is no evidence that the Company will have sufficient taxable income to utilize these carryforwards. As a result, any loss of deductions in these tax filing jurisdictions is unlikely to result in an adjustment to the Company's net deferred tax assets or liabilities.

The Company is currently conducting a study of its U.S. NOL carryforwards incurred subsequent to December 31, 2005 to determine whether such amounts are limited in terms of how quickly they can be used under Internal Revenue Code Section 382. The Company does not believe the limitations would, if applicable, significantly impact its ability to offset future taxable income with available NOLs.

9. Discontinued Operations

On April 12, 2007, the Company sold its former subsidiary, AION Diagnostics Limited ("AION"), to GEM Global Yield Fund ("GEM"). Total consideration included cash payments totaling \$1.85 million and a \$1.5 million promissory note, bearing 8% annual interest compounded monthly. The promissory note was due April 12, 2008, but has not yet been paid and is overdue (see Note 11).

The operating results of AION for the three and nine months ended March 31, 2007 were included as discontinued operations in the accompanying unaudited condensed consolidated financial statements. During those periods, AION generated no revenues and there was no income tax benefit associated with its operating loss.

10. Comprehensive Loss

Comprehensive loss for the three and nine months ended March 31, 2008 and 2007 is as follows:

		Three Months Ended Nine I March 31,		
	2008 (In the	2007 ousands)	2008 (In tho	2007 isands)
Net loss	\$(5,501)	\$(12,197)	\$(12,091)	\$(43,256)
Foreign currency translation adjustments	(74)	2,613	(241)	6,752
Comprehensive loss	\$(5,575)	\$ (9,584)	\$(12,332)	\$(36,504)

11. Subsequent Events

On April 16, 2008, the Company issued a formal notice of default to GEM in connection with a \$1.5 million unsecured promissory note and accrued and unpaid interest of \$125,000. These amounts were payable by GEM on April 12, 2008 (see Note 9). The Company is pursuing its legal rights.

On April 18, 2008, the Company announced that it proposes to reincorporate in the United States. The reincorporation, which is subject to Australian Federal Court and shareholder approval, is scheduled to occur in mid-2008. If the reincorporation is approved, all outstanding shares of the Company will be transferred to a new company incorporated in the U.S, which will then become the new parent company of the pSivida group. In exchange, the new U.S. company will issue one of its common shares for each 4 ADSs of the Company and one CHESS Depositary Interest ("CDI") for each 40 ordinary shares of the Company, with cash to be paid in lieu of issuing fractional shares. Shares of the new US company will be listed on NASDAQ and the Frankfurt Stock Exchange, and CDIs will be listed on the ASX and Frankfurt Stock Exchange. All assets and liabilities of the Company will be transferred to, and assumed by, the new US company. Outstanding options and warrants will be equitably adjusted to reflect the reincorporation. Shares in the Company's subsidiaries will be transferred to the new US company. As part of the reincorporation, pSivida Limited will be deregistered without a winding up.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Note Regarding Forward-Looking Statements

Various statements made in this Quarterly Report on Form 10-Q are forward-looking and involve a number of risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. The following are some of the factors that could cause actual results to differ materially from the forward-looking statements: the scheme of arrangement for reincorporation of the company, including whether or not it is implemented; the achievement of milestones and other contingent contractual payment events; failure to prove efficacy for BrachySil; inability to raise capital; continued losses and lack of profitability; inability to develop or obtain regulatory approval for new products; inability to protect intellectual property or infringement of others' intellectual property; inability to obtain partners to develop and market products; termination of license agreements; competition; inability to pay any registration penalties; costs of international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; inability to manage change; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; amortization or impairment of intangibles; issues relating to Australian incorporation; potential inability to retain the independent auditor; potential delisting from the Australian Securities Exchange ("ASX") or NASDAQ; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; potential restrictions from capital raises; possible influence by Pfizer; and other factors that may be described in our filings with the Securities and Exchange Commission ("SEC"). These risks and uncertainties are discussed in Item 3.D. "Risk Factors" in our Annual Report on Form 20-F for the fiscal year ended June 30, 2007, in Item 1A. "Risk Factors" in this Form 10-Q and in our other filings with the SEC. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. We do not undertake to publicly update or revise our forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied in such statements will not be realized.

Our Business

We are a global drug delivery company committed to the biomedical sector and the development of therapeutic delivery products. Retisert® is approved by the U.S. Food and Drug Administration ("FDA") for the treatment of posterior uveitis. Vitrasert® is FDA approved for the treatment of AIDS-related CMV retinitis. The Company has licensed the technologies underlying both of these products to Bausch & Lomb Incorporated. The technology underlying the Medidur™ for diabetic macular edema ("DME") product candidate using fluocinolone acetonide ("Medidur FA for DME") is licensed to Alimera Sciences and is in Phase III clinical trials. The Company has a worldwide collaborative research and license agreement with Pfizer for certain of the Company's technologies, including the technology underlying Medidur, in certain ophthalmic applications.

We own the rights to develop and commercialize a novel-porous biomaterial composed of nanostructured elemental silicon, known as BioSiliconTM, which has potential applications in drug delivery, wound healing, orthopedics and tissue engineering. The most advanced BioSilicon product, BrachySilTM, delivers phosphorus-32, a beta-emitting radioactive isotope shown to shrink tumors, directly to solid tumors. We recently completed a Phase IIa clinical trial of BrachySilTM for the treatment of pancreatic cancer and expect to shortly begin a Phase IIb dose-ranging clinical trial.

BioSiliconTM, BrachySilTM and MedidurTM are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks.

Summary of Critical Accounting Policies

We prepare our consolidated financial statements in accordance with U.S. GAAP. In preparing these financial statements, we make certain estimates, judgments and assumptions that 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. These estimates, judgments and assumptions, which management believes are reasonable under the circumstances and are based upon the information available at the time, cannot be made with certainty. These estimates, judgments and assumptions may change as new events occur or as additional information is obtained, and actual results may differ from these estimates under different assumptions or conditions. While there are a number of accounting policies, methods and estimates affecting our financial statements as described in Note 2 to the accompanying unaudited condensed consolidated financial statements, management has identified certain of these accounting policies to be critical to aid in a full understanding and evaluation of our financial condition and results of operations. A critical accounting policy is one that is both material to the presentation of our financial statements and requires us to make subjective or complex judgments that could have a material effect on our financial condition and results of operations. We believe the following critical accounting policies, and our procedures relating to these policies, require more significant judgments and estimates in the preparation of our consolidated financial statements.

Revenue Recognition for License Agreements

The Company has entered into collaborative license and development arrangements with strategic partners for the development and commercialization of products utilizing the Company's technologies. The terms of these agreements typically include multiple deliverables by the Company (for example, license rights, providing research and development services and manufacturing of clinical materials) in exchange for consideration to the Company of some combination of non-refundable license fees, funding of research and development activities, payments based upon achievement of clinical development milestones and royalties in the form of a designated percentage of product sales or profits. The Company follows the provisions of the Securities and Exchange Commission's Staff Accounting Bulletin ("SAB") No. 101 ("SAB 101"), "Revenue Recognition in Financial Statements", as amended by SAB No. 104 ("SAB 104"), "Revenue Recognition", and Emerging Issues Task Force ("EITF") Issue No. 00-21 ("EITF 00-21"), "Accounting for Revenue Arrangements with Multiple Deliverables". With the exception of royalties, these types of consideration are classified as collaborative research and development revenue in the Company's statements of operations when revenue recognition is appropriate.

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

For arrangements that are accounted for as a single unit of accounting, total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, are recognized as revenue on a straight-line basis over the period the Company expects to complete its performance obligations. The cumulative amount of revenue earned is limited to the cumulative amount of payments received as of the period ending date.

If the Company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential, then revenue is deferred until the Company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance. Deferred revenue amounts are classified as current liabilities to the extent that revenue is expected to be recognized within one year.

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

Amended and Restated Collaboration Agreement with Alimera Sciences, Inc.

As discussed in Note 4 to the accompanying unaudited condensed consolidated financial statements, we entered into an amended collaboration agreement with Alimera on March 14, 2008. The terms and conditions of this amendment required an assessment of the expected term of the agreement and our obligations thereunder. Pursuant to EITF 00-21, we evaluated the Company's obligations under the amended agreement and concluded that, since each deliverable did not have a determinable fair value to the licensee on a standalone basis, such deliverables represented a single unit of accounting. The Company further determined that all of its consequential development obligations under the amended agreement would cease no later than December 31, 2009. Accordingly, commencing on the effective date of the amended agreement, the Company will amortize the aggregate \$18.3 million deferred revenue balance that existed at that date on a straight-line basis over the 21.5 month performance period. The \$18.3 million deferred revenue balance consisted of (i) a \$12.0 million payment received upon the execution of the amended agreement; (ii) cancellation of approximately \$5.7 million of accrued development costs, including related penalties and accrued interest, owed by the Company to Alimera as of March 14, 2008; and (iii) an additional \$650,000 of previously received but unamortized milestone payments.

All future payments received from Alimera during the designated performance period will be recognized as revenue using the cumulative catch-up method. Under this method, the portion of any such payment represented by the time elapsed from the amendment effective date to the payment date as a percentage of the 21.5 month performance period will be recognized immediately as revenue, with the remainder amortized on a straight-line basis over the remaining performance period. All payments received from Alimera following the end of the performance period will be recognized as revenue when earned.

Pfizer Collaborative Research and License Agreement

On April 3, 2007, the Company and Pfizer, Inc. entered into a Collaborative Research and License Agreement (the "Pfizer Agreement") which superseded a prior research agreement dated December 22, 2006. Under the Pfizer Agreement, the parties have implemented a joint research program aimed at developing ophthalmic products using the Company's Durasert drug delivery technology. In addition to potential development and sales related milestone payments, Pfizer will pay the Company \$500,000 per quarter, commencing in calendar year 2008, in consideration of the Company's costs in performing the research program, and continuing until the commencement of a Phase III clinical trial for the first licensed product candidate or until the agreement is earlier terminated. Pfizer made the first \$500,000 research payment in February 2008.

The two Pfizer agreements have been combined for accounting purposes and, following an evaluation of the multiple deliverables in accordance with the provisions of EITF 00-21, the Company concluded that there was a single unit of accounting. The Company is currently evaluating the deliverables and other obligations under the Pfizer Agreement and, as a result, all payments received to date from Pfizer totaling \$1.25 million have been recorded as deferred revenue.

Intrinsiq License Agreement

On January 17, 2008, the Company and Intrinsiq entered into an agreement pursuant to which Intrinsiq acquired an exclusive license to develop and commercialize nutraceutical and food science applications of BioSilicon, and certain related assets, for \$1,230,000. Intrinsiq paid \$500,000 at closing and agreed to make additional payments totaling \$730,000 through January 2009. In addition, subject to its unilateral right to terminate the license upon 90 days prior written notice, Intrinsiq will be obligated to pay the Company minimum royalties of \$3.95 million over five years, of which the first \$500,000 payment is due 18 months after the closing.

The Company is required to spend approximately \$460,000 to expand the Company's BioSilicon manufacturing capacity and is obligated to enter into a supply agreement with Intrinsiq. The Company does not believe that the agreement to execute a supply agreement has standalone value to Intrinsiq. Therefore, until the supply agreement is executed, the Company is unable to estimate the period of its performance obligations under the license agreement. The aggregate total of \$1.2 million, consisting of cash received and contractual amounts due from Intrinsiq, has been recorded as deferred revenue at March 31, 2008, and will not be subject to revenue recognition until the Company can determine the end date of its performance obligations.

Intangible Assets and Goodwill

Intangible assets acquired in a business combination

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

In connection with our acquisition of CDS referred in Note 2 of our unaudited condensed consolidated financial statements, we determined that the portion of the CDS purchase price allocation assigned to Medidur met the definition of in-process research and development, or IPR&D, as the product was in Phase III clinical trials, had not been approved by the FDA and did not have alternative future use other than the indications for which it was in development. As such, the value assigned to Medidur was immediately expensed on the acquisition date in accordance with FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method.*

The portion of the purchase price allocation assigned to Retisert, which was a commercially available product approved for sale by the FDA at the date of the CDS acquisition, is subject to amortization over the estimated useful life of the intangible asset. We evaluated several pertinent factors to determine an appropriate useful life. These included:

- the Retisert for Uveitis patents will be further commercialized as we advance other development programs using these patents for similar drug delivery devices for other eye diseases;
- the acquired intellectual property is not related to another asset or asset group that could limit its life;
- the acquired patents have a legal expiration of 12 to 15 years from the date of acquisition and we are unaware of any regulatory or contractual
 provisions that would limits their lives;

- · the potential for product obsolescence as a result of competition and the financial limitations on our product development capabilities; and
- · the minimal expected costs of ongoing patent maintenance.

On the basis of these and other considerations, our judgment was that the acquired patents had an estimated useful life of 12 years from the date of acquisition.

Goodwill

Goodwill arising on consolidation consists of the excess of the cost of the acquisition over our interest in the fair value of the identifiable assets and liabilities at the date of acquisition. The excess of the purchase price over the fair value of the assets and liabilities of CDS acquired on December 30, 2005, \$30.5 million, was recorded as purchased goodwill and is subject to testing for impairment on at least an annual basis. In applying impairment testing, our judgment was that the consolidated entity is the deemed reporting unit. In making this determination we considered that (1) we operate in one business segment, the biotechnology sector; and (2) our executive management assesses operating performance and reviews financial statements predominantly at the consolidated level.

The Company is required to test for goodwill impairment on an annual basis (June 30 of each year) and whenever events or changes in circumstances indicate that the carrying value may no longer be recoverable. For the analysis at June 30, 2007, the cash flow projections were based on the expectations and forecasts of management covering a 10.5 year period (the remaining estimated useful life of the Company's patents) and applying a discount rate equal to a weighted average cost of capital for the Company of approximately 17.5%. Management believes the estimated useful life to be a reasonable period to consider based on the nature of the industry and the often long product development cycles prior to commercialization. Cash flows were estimated based on current numbers of patients diagnosed with the condition which the Company's products are developed to treat, with growth rates based on generally expected trends, ranging between 0% and 4% per annum. Management considers such growth rates to be reasonable. Market penetration rates were developed based on currently available sales results and on management's future expectations and range from between 0.4% to 12%. Management considers the market penetration rates applied to be reasonable based on the unmet need of the conditions for which the Company's products are being developed to treat. Development costs were estimated based on historical costs and on management's development plans currently in place, with general and administrative costs assumed to grow at the rate of 5% per annum after the three year period for which detailed cost budgets were prepared by management.

Impairment of Intangible Assets

The Company reviews its intangible assets for impairment whenever events or other changes in circumstances indicate that the carrying value of an asset may no longer be recoverable. At December 31, 2006 and at June 30, 2007, the Company identified triggering events that required in-depth assessment of the recoverability of the carrying value of its Retisert and BrachySil intangible assets. The valuation assessment required detailed analysis of projected future cash inflows and cash outflows associated with each intangible asset. These projections required the application of numerous judgments. In the case of Retisert, a commercialized product with two years of sales history, these judgments and estimates included market penetration rates, estimated market growth, potential impact of new technologies under development, penetration rate for re-implants and appropriate weighted average cost of capital rate to discount the future cash flows. In the case of BrachySil, a product candidate then in Phase IIa clinical trial, other estimates included the cost and duration of later stage clinical trials, timing of regulatory approval and the probability of a collaboration agreement with a third party.

At June 30, 2007, the Company recorded an impairment write-down of \$45.3 million in connection with its Retisert patents. No impairment write-downs were required at December 31, 2006.

If the actual cash flows are significantly different from the projected amounts, the Company may be required to record additional impairment write-downs against the \$37.8 million of carrying value of its intangible assets at March 31, 2008.

Accounting for Convertible Notes

The Company financed its activities partially through the issuance of convertible notes with detachable warrants in November 2005 and September 2006 to institutional investors. These compound instruments require analysis of their component parts and appropriate classification as liabilities and equity. We concluded that the note holder conversion option was an embedded derivative that required bifurcation and classification as a derivative liability subject to fair value adjustment through the consolidated statements of operations. The fair value of the embedded derivative was estimated using the Binomial Tree Model, taking into account assumptions as to share price volatility, dividend yield and market interest rates for a comparable non-convertible debt instrument.

The initial carrying value of a convertible note liability is determined by first subtracting from the gross proceeds the relative fair value of any equity component and then subtracting the fair value of any compound embedded derivatives. The effective interest method is used to amortize to finance costs the debt discount over the expected life of the financial liability, or such shorter period as may be deemed appropriate. Debt issue costs are recorded as an asset and similarly amortized to finance costs over the life of the financial liability.

During the year ended June 30, 2007, the Company entered into multiple amendments of the terms of the Sandell convertible note. For each amendment, the Company estimated the present value of the future cash flows of the amended note, including cash and non-cash consideration, against that of the preamendment note. If the resulting present values reflected a change of greater than 10%, the pre-amendment note was accounted for as an extinguishment of debt and the issuance of a new compound debt instrument. Alternatively, if the resulting present values reflected a change of less than 10%, the amendment was treated as a modification of the original debt instrument. As more fully described in Note 6 of the accompanying unaudited condensed consolidated financial statements, during the nine months ended March 31, 2007, the Company entered into three amendments of its Sandell convertible note, two of which resulted in extinguishment of the prior debt instrument and one of which was treated as a debt modification.

Accounting for Business Combinations

We account for business combinations using the purchase method of accounting and, accordingly, the assets and liabilities of the acquired entity are recorded at their estimated fair values at the date of acquisition. Cost is measured as the fair value of the assets given, shares issued or liabilities incurred or assumed at the date of exchange plus costs directly attributable to the acquisition. The excess of the cost of acquisition over the fair value of the identifiable net assets acquired is recorded as goodwill.

In applying the purchase method to our acquisition of CDS, we made various estimates and assumptions concerning the valuation of the consideration paid by us and the fair values of the assets and liabilities of CDS. These included the following considerations:

- We determined the volume weighted average closing price of the Company's NASDAQ-listed ADSs for the period from two days before until two days after definitive announcement of the transaction to be the appropriate value of the shares given in the acquisition.
- We determined that the issue of 1,211,180 non-vested ordinary shares in connection with employee retention was not in exchange for existing awards held by CDS employees, and, accordingly, the entire fair value of these non-vested shares was considered unearned compensation to be expensed over the future service (vesting) period and not part of the purchase consideration.
- We determined that the value of 8,991,930 non-vested ordinary shares issued in exchange for non-vested CDS common shares outstanding should not be discounted from the fair value per share determined for the vested ordinary shares on the basis that (1) the holders had the same rights as normal holders of ordinary shares and (2) the Company's estimate was that all of the underlying shares would vest.
- We estimated the fair value of share-based payments for the issuance of 1,724,460 vested share options in exchange for the outstanding vested CDS options.
- We estimated the value of identifiable intangibles of CDS (Vitrasert, Retisert and Medidur) utilizing the discounted value of projected cash flows. We reviewed the estimated future cash flows and the discount rates used to calculate a present value. The patents supporting Vitrasert were given no value based upon the judgment that the incidence of the disease to which the application of this technology relates had significantly decreased due to advancements in the treatment of AIDS. Projected cash flows for Medidur were adjusted downwards after applying an estimated probability of successful commercialization in light of that product's then current stage of development. As a result of these analyses, the value ascribed to patents was associated with Retisert, and the value attributed to in-process research and development was related to Medidur.

Results of Operations

Three Months Ended March 31, 2008 Compared to Three Months Ended March 31, 2007:

		nths Ended		
		rch 31,	Chang	
	2008	2007	Amount	<u>%</u>
Revenues	\$ 542	n thousands excep \$ 369	\$ 173	47%
Operating expenses:		<u> </u>		
Research and development	3,605	5,153	(1,548)	(30)%
Selling, general and administrative	3,546	2,064	1,482	72%
Total operating expenses	7,151	7,217	(66)	(1)%
Loss from operations	(6,609)	(6,848)	239	(3)%
Other income (expense):				
Change in fair value of derivative	1,172	(6,673)	7,845	(118)%
Interest income	121	62	59	95%
Interest and finance costs	(206)	(1,962)	1,756	(90)%
Other	6	39	(33)	(85)%
Total other income (expense)	1,093	(8,534)	9,627	(113)%
Loss from continuing operations before income taxes	(5,516)	(15,382)	9,866	(64)%
Deferred income tax benefit	15	3,544	(3,529)	(100)%
Net loss from continuing operations	(5,501)	(11,838)	6,337	(54)%
Net loss from discontinued operations		(359)	359	na
Net loss	\$(5,501)	\$(12,197)	\$ 6,696	(55)%

na = not applicable

Revenue

Revenue increased by \$173,000, or 47%, to \$542,000 for the three months ended March 31, 2008 from \$369,000 for the three months ended March 31, 2007. The increase was primarily attributable to \$426,000 of revenue recognized in connection with the amended collaboration agreement with Alimera consummated on March 14, 2008, partially offset by a \$220,000 decrease in royalty income payable to the Company by Bausch & Lomb on its sales of Retisert.

The Company recorded approximately \$18.3 million of deferred revenue at the effective date of the Alimera amendment (see Note 4 of the unaudited condensed consolidated financial statements), which will be recognized to revenue ratably over the performance period through December 2009, or approximately \$2.5 million per quarter. Additional consideration received by the Company pursuant to the Alimera agreement prior to December 31, 2009 will also be recognized ratably over the performance period, including immediate revenue recognition for the pro rata period from the effective date to the date of receipt.

Pursuant to a June 2005 advance royalty agreement, Bausch & Lomb has retained (a) 50% of Retisert royalties otherwise payable to the Company through June 30, 2007 and (b) 100% of Retisert royalties otherwise payable to the Company subsequent to June 30, 2007. Subsequent to March 31, 2008, Bausch & Lomb is entitled to retain an additional \$3.3 million of future Retisert royalties otherwise payable to the Company. Accordingly we currently do not expect to receive any Retisert royalty income from Bausch & Lomb through at least the fiscal year ending June 30, 2009.

Royalties retained by Bausch & Lomb pursuant to the advance royalty agreement which would otherwise have been payable to the Company for the three months ended March 31, 2008 were \$371,000. This was a 20% decrease from \$461,000 paid or otherwise payable to the Company in the same quarter a year earlier and a 31% decrease from \$541,000 otherwise payable to the Company in the immediately preceding quarter.

Research and Development

Research and development decreased by approximately \$1.5 million, or 30%, to approximately \$3.6 million for the three months ended March 31, 2008 from approximately \$5.2 million for the three months ended March 31, 2007. This decrease was primarily attributable to the following factors:

- a decrease of approximately \$1.1 million in amortization of intangible assets due to the effect of the \$45.3 million asset impairment write-down at June 30, 2007 related to our Retisert patents; and
- a decrease of approximately \$600,000 in our U.K. and Singapore-based operating expenses as a result of (i) personnel reductions in the U.K. which were implemented as cost reduction measures and (ii) reduced depreciation expense; which were partially offset by
- an increase of approximately \$200,000 in development costs related to the Phase III clinical trial of the Medidur FA for DME product candidate through the March 14, 2008 effective date of the Company's amended collaboration agreement with Alimera.

Development costs related to the Phase III clinical trial of the Medidur FA for DME product candidate, which totaled approximately \$1.2 million for the three months ended March 31, 2008, will not be incurred in future periods pursuant to the terms of the amended collaboration agreement with Alimera.

Selling, General and Administrative

Selling, general and administrative costs increased by approximately \$1.5 million, or 72%, to approximately \$3.5 million for the three months ended March 31, 2008 from approximately \$2.1 million for the three months ended March 31, 2007. This increase was primarily attributable to the following factors:

- an increase of approximately \$1.0 million in legal fees, primarily related to (a) the Company's proposal to reincorporate in the United States and (b) collaboration agreements; and
- · an increase of approximately \$275,000 in share-based payments expense, primarily due to the effect of prior year period forfeitures.

Change in Fair Value of Derivative

Change in fair value of derivative represented income of approximately \$1.2 million for the three months ended March 31, 2008 compared to expense of approximately \$6.7 million for the three months ended March 31, 2007.

For the three months ended March 31, 2008, the change in fair value of derivative was related to warrants issued in financing transactions denominated in A\$ and resulted in income of approximately \$1.2 million primarily due to a decrease in the market price of our ordinary shares during that period. These derivative liabilities will be subject to future revaluation through expiration, or earlier exercise, of the underlying warrants. Several factors, primarily decreases or increases in the Company's ordinary share price, will result in income or expense amounts, respectively, to be recorded in future periods.

For the three months ended March 31, 2007, the change in fair value of derivative consisted of (a) approximately \$4.5 million of expense related to the embedded conversion features of our convertible notes, which were redeemed in full prior to June 30, 2007 and (b) approximately \$2.2 million of expense related to warrants issued in financing transactions denominated in A\$. The expense amounts were primarily attributable to an increase in the market price of our ordinary shares during that period.

Interest Income

Interest income increased by approximately \$59,000, or 95%, to \$121,000 for the three months ended March 31, 2008 from \$62,000 for the three months ended March 31, 2007. This increase was attributable to (i) interest earned on cash equivalent balances resulting from the July 2007 share issue as described in Note 3 of our unaudited condensed consolidated financial statements and (ii) interest accrued on the \$1.5 million note receivable due April 2008 in connection with the April 2007 sale of our former subsidiary, AION Diagnostics Limited, the principal and interest of which has not been paid and is overdue (see Note 11 to the accompanying unaudited condensed consolidated financial statements).

Interest and Finance Costs

Interest and finance costs were \$206,000 for the three months ended March 31, 2008 compared to approximately \$2.0 million for the three months ended March 31, 2007. The decrease in interest and finance costs of approximately \$1.8 million was primarily attributable to the absence in the current period of (i) approximately \$370,000 of interest expense and approximately \$1.3 million of amortization of debt discount and issue costs in connection with convertible notes which were subsequently redeemed prior to June 30, 2007 and (ii) approximately \$147,000 of registration rights delay penalties. As of June 30, 2007, all required registration statements had been filed and declared effective by the SEC. In addition, for the three months ended March 31, 2008 and 2007, we accrued approximately \$205,000 and \$150,000 of interest expense, respectively, on the portion of shared Medidur FA for DME product candidate development costs that we elected not to pay. In connection with the amended collaboration agreement with Alimera, the total development costs, including associated penalties and accrued interest, owed by the Company to Alimera were cancelled. The Company does not expect to incur any interest and finance costs for the remainder of the fiscal year ending June 30, 2008.

Deferred Income Tax Benefit

Deferred income tax benefit decreased to \$15,000 for the three months ended March 31, 2008 from \$3.5 million for the three months ended March 31, 2007. The primary reason for the smaller benefit in the current period is that since June 30, 2007 valuation allowances have been required to offset essentially all net operating loss carryforwards created during the current period, which was not the case for the earlier period. The limitation on the ability to record deferred tax assets since June 30, 2007 was primarily attributable to the significant impairment write-down (and resulting decrease in the deferred tax liabilities) recorded in June 2007 related to the Retisert patents.

Nine Months Ended March 31, 2008 Compared to Nine Months Ended March 31, 2007:

	Nine Mon Maro		Chang	io.
	2008	2007	Amount	%
	(Ir	thousands except	percentages)	
Revenues	\$ 773	\$ 1,483	\$ (710)	(48)%
Operating expenses:				
Research and development	12,022	16,877	(4,855)	(29)%
Selling, general and administrative	8,609	8,272	337	4%
Total operating expenses	20,631	25,149	(4,518)	(18)%
Loss from operations	(19,858)	(23,666)	3,808	(16)%
Other income (expense):				
Change in fair value of derivative	7,193	(4,606)	11,799	(256)%
Interest income	534	152	382	251%
Interest and finance costs	(507)	(8,823)	8,316	(94)%
Loss on extinguishment of debt	_	(12,147)	12,147	na
Other	308	95	213	224%
Total other income (expense)	7,528	(25,329)	32,857	(130)%
Loss from continuing operations before income taxes	(12,330)	(48,995)	36,665	(75)%
Deferred income tax benefit	239	7,033	(6,794)	(97)%
Net loss from continuing operations	(12,091)	(41,962)	29,871	(71)%
Net loss from discontinued operations		(1,294)	1,294	na
Net loss	\$(12,091)	\$(43,256)	\$31,165	(72)%

na = not applicable

Revenue

Revenue decreased by \$710,000, or 48%, to \$773,000 for the nine months ended March 31, 2008 from \$1.5 million for the nine months ended March 31, 2007. The decrease was primarily attributable to a \$671,000 reduction in royalty income payable to the Company by Bausch & Lomb on its sales of Retisert. In connection with an advance royalty agreement entered into with Bausch & Lomb in June 2005, royalties otherwise payable to the Company were retained by Bausch & Lomb for the nine months ended March 31, 2008.

Royalties paid or otherwise payable to the Company from Bausch & Lomb for each of the nine months ended March 31, 2008 and 2007 were approximately \$1.4 million.

Research and Development

Research and development decreased by approximately \$4.9 million, or 29%, to approximately \$12.0 million for the nine months ended March 31, 2008 from approximately \$16.9 million for the nine months ended March 31, 2007. This decrease was primarily attributable to the following factors:

- a decrease of approximately \$4.3 million in amortization of intangible assets due to the effects of (i) the \$45.3 million asset impairment write-down at June 30, 2007 related to our Retisert patents and (ii) the revision of the expected useful life for our BrachySil intangible assets from 7 years to 11 years effective as of December 31, 2006; and
- a decrease of approximately \$1.9 million in our U.K. and Singapore-based operating expenses as a result of (i) personnel reductions in the U.K. which were implemented as cost reduction measures and (ii) reduced depreciation expense related to a clean room facility that was fully depreciated at June 30, 2007; which were partially offset by
- · an increase of approximately \$2.0 million in development costs related to the Phase III clinical trial of the Medidur FA for DME product candidate.

Selling, General and Administrative

Selling, general and administrative costs increased by approximately \$337,000, or 4%, to approximately \$8.6 million for the nine months ended March 31, 2008 from approximately \$8.3 million for the nine months ended March 31, 2007. This increase was primarily attributable to the following factors:

- an increase of approximately \$1.0 million in legal fees, primarily attributable to (a) the Company's proposal to reincorporate in the United States; (b) collaboration agreements; and (c) patents; and
- approximately \$200,000 of current period costs incurred for market development research for certain product candidates; which were partially offset by
- a decrease of approximately \$350,000 of personnel and related costs related to our Australian operations resulting from the consolidation of functions in Boston, Massachusetts;
- a decrease of approximately \$200,000 in audit and audit related fees; and
- the absence of approximately \$250,000 in fees incurred in the prior year period for financing transaction alternatives that were not consummated.

Change in Fair Value of Derivative

Change in fair value of derivative represented income of approximately \$7.2 million for the nine months ended March 31, 2008 compared to expense of approximately \$4.6 million for the nine months ended March 31, 2007.

For the nine months ended March 31, 2008, the change in fair value of derivative was related to warrants issued in financing transactions denominated in A\$ and resulted in income of approximately \$7.2 million primarily due to a decrease in the market price of our ordinary shares during that period. These derivative liabilities will be subject to future revaluation through expiration, or earlier exercise, of the underlying warrants. Several factors, primarily decreases or increases in the Company's ordinary share price, will result in income or expense amounts, respectively, to be recorded in future periods.

For the nine months ended March 31, 2007, the change in fair value of derivative consisted of (a) approximately \$2.4 million of expense related to the embedded conversion features of our convertible notes, which were redeemed in full prior to June 30, 2007 and (b) approximately \$2.2 million of expense related to warrants issued in financing transactions denominated in A\$. The expense amounts were primarily attributable to an increase in the market price of our ordinary shares during the nine months ended March 31, 2007.

Interest Income

Interest income increased by approximately \$382,000, or 251%, to \$534,000 for the nine months ended March 31, 2008 from \$152,000 for the nine months ended March 31, 2007. This increase was attributable to (i) interest earned on cash equivalent balances resulting from the July 2007 share issue and (i) interest accrued on the \$1.5 million note receivable due April 2008 in connection with the April 2007 sale of our former subsidiary, AION Diagnostics Limited, the principal and interest of which has not been paid and is overdue (see Note 11 to the accompanying unaudited condensed consolidated financial statements).

Interest and Finance Costs

Interest and finance costs were approximately \$507,000 for the nine months ended March 31, 2008 compared to approximately \$8.8 million for the nine months ended March 31, 2007. The decrease in interest and finance costs of approximately \$8.3 million was primarily attributable to the absence in the current period of (i) approximately \$1.1 million of interest expense and approximately \$4.7 million of amortization of debt discount and issue costs in connection with convertible notes which were redeemed prior to June 30, 2007 and (ii) approximately \$2.6 million of registration rights delay penalties. As of June 30, 2007, all required registration statements had been filed with and declared effective by the SEC. In addition, for the nine months ended March 31, 2008 and 2007, we accrued approximately \$507,000 and \$409,000 of interest expense, respectively, on the portion of shared Medidur FA for DME product candidate development costs that we elected not to pay. In connection with the amended collaboration agreement with Alimera, the total deferred development costs, including associated penalties and accrued interest, owed by the Company to Alimera were cancelled. The Company does not expect to incur any interest and finance costs for the remainder of the fiscal year ending June 30, 2008.

Loss on Extinguishment of Debt

Loss on extinguishment of debt totaled approximately \$12.1 million for the nine months ended March 31, 2007. In September 2006, we amended the terms of the convertible promissory note issued to Sandell in November 2005. The terms of the amendment agreement met the criteria that required the original note to be accounted for as an extinguishment of debt and the amended note to be accounted for as the issuance of a new convertible debt instrument. The terms of the amendment included consideration issued to Sandell of (i) warrants to purchase 5.7 million ADS (valued at \$8.7 million using the Binomial Tree Model); and (ii) the payment of \$1.0 million in cash. The calculation of the loss on extinguishment included the cash and non-cash consideration issued to Sandell. In December 2006, we entered into a second amendment agreement in connection with the Sandell convertible note. The terms of the second amendment agreement met the criteria that required the previously amended note to be accounted for as an extinguishment of debt and the second amended note to be accounted for as the issuance of a new convertible debt instrument. The terms of the amendment included the issuance to Sandell of additional warrants to purchase 1.5 million ADSs (valued at \$1.7 million using the Binomial Tree Model). The calculation of the loss on extinguishment included the value of this non-cash consideration issued to Sandell. The Company's convertible notes were redeemed in full prior to June 30, 2007 and, accordingly, there is no loss from extinguishment of debt in the current year period.

Other Income

Other income increased by approximately \$213,000, or 224%, to \$308,000 for the nine months ended March 31, 2008 from \$95,000 for the nine months ended March 31, 2007. This increase consisted of approximately \$405,000 of income attributable to a revenue sharing arrangement with the provider of the Company's ADR program, partially offset by net foreign exchange losses of approximately \$100,000.

Deferred Income Tax Benefit

Deferred income tax benefit decreased to \$239,000 for the nine months ended March 31, 2008 from approximately \$7.0 million for the nine months ended March 31, 2007. The primary reason for the smaller benefit in the current period is that since June 30, 2007 valuation allowances have been required to offset essentially all net operating loss carryforwards created during the current period, which was not the case for the earlier period. The limitation on the ability to record deferred tax assets since June 30, 2007 was primarily attributable to the significant impairment write-down (and resulting decrease in the deferred tax liabilities) recorded in June 2007 related to the Retisert patents.

Liquidity and Capital Resources

We have incurred operating losses since inception and, at March 31, 2008 we had a total accumulated deficit of \$161.0 million. Our research and development and selling, general and administrative costs, in the aggregate, have exceeded our revenues, including revenues related to our two commercialized products, and, accordingly, our operations have historically generated negative cash flows. Although we generated positive cash flows from operations for the three months ended March 31, 2008, primarily due to the \$12.0 million up front cash proceeds from the amended collaboration agreement with Alimera, we generally expect negative cash flows from operations on a quarterly basis at least until such time as one or more of our product candidates achieves regulatory approval and commences commercial sales. Since our inception, we have relied primarily on sales of our equity and debt securities and the proceeds from license fee and collaboration payments to fund our operations.

Cash and cash equivalents totaled approximately \$18.2 million at March 31, 2008 compared to \$2.7 million at June 30, 2007. We currently believe that if the Pfizer and Alimera agreements continue and we receive the Pfizer research and development funding, Alimera continues to fund the development of Medidur FA and we receive the scheduled conditional note payments from Alimera, our existing cash resources together with these payments will be sufficient to fund our operations under our current operating plan through at least June 30, 2010. If we receive Alimera or Pfizer milestone payments or our Retisert royalties resume during that period, our operations would be funded for a longer period.

The timing and amount of our future capital requirements will depend upon many other factors, including, but not limited to:

- the continuation of, and payments under, our existing collaboration and license agreement with Pfizer, Alimera and others, including their continued funding of our programs and our receipt of milestone, royalty, note and other payments, and the development of new collaboration and licensing agreements for other product candidates, such as BrachySil;
- the amount and timing of sales of Retisert, which affects the timing of resumption of Retisert royalty payments, and the amounts of such royalty payments;
- · the scope and extent of our internally funded operations, including our programs for BrachySil and other BioSilicon product candidates;
- our ability to establish and maintain strategic arrangements (in addition to those set forth above) for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved
 products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- changes in our current operating plan, which may affect our need for capital; and
- the consummation of our proposed reincorporation.

If we require additional financing, we do not know if it will be available when needed or on terms favorable to us or our stockholders. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, or funding through collaboration agreements may be on unfavorable terms including requiring us to relinquish rights to our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, or otherwise reduce our cash requirements.

Our consolidated statements of cash flows for the nine months ended March 31, 2008 and 2007 are summarized as follows:

	2008	2007 (In thousands)	Change
Net loss:	\$(12,091)	\$(43,256)	\$ 31,165
Changes in operating assets and liabilities	12,919	1,043	11,876
Other adjustments to reconcile net loss to cash flows from operating activities	(3,531)	24,553	(28,084)
Cash flows used in operating activities	\$ (2,703)	\$(17,660)	\$ 14,957
Cash flows used in investing activities	\$ (133)	\$ (71)	\$ (62)
Cash flows provided by financing activities	\$ 18,387	\$ 12,490	\$ 5,897

Net cash used in operating activities totaled approximately \$2.7 million for the nine months ended March 31, 2008 compared to approximately \$17.7 million for the nine months ended March 31, 2007. The decrease in cash used in operations of approximately \$15.0 million was primarily attributable to (a) \$13.0 million cash received in the current year period from various license and collaboration agreements, primarily the \$12.0 million payment from Alimera on March 14, 2008; (b) the absence in the current period of \$2.3 million of interest expense and registration rights penalties in connection with our convertible notes; and (c) a reduction of approximately \$1.3 million of salaries and related benefits as a result of staff reductions in our U.K. operations, the consolidation of functions from Perth, Australia to Boston, Massachusetts and the sale of AION Diagnostics Limited in April 2007, all undertaken as part of the Company's cost reduction efforts; which were partially offset by (x) an increase of approximately \$900,000 in development costs of Medidur FA for DME paid to Alimera Sciences; and (y) a reduction of \$240,000 in Retisert and Vitrasert royalties.

Net cash used in investing activities, which increased by \$62,000, consisted entirely of purchases of property and equipment. Net cash flows provided by financing activities totaled approximately \$18.4 million for the nine months ended March 31, 2008 compared to approximately \$12.5 million for the nine months ended March 31, 2007. During the nine months ended March 31, 2008, we sold 164,567,945 ordinary shares (consisting of 14,402,000 ADSs and 20,547,945 ordinary shares) for net proceeds of approximately \$18.4 million. Pfizer purchased 5,200,000 ADSs (52,000,000 equivalent ordinary shares) of that total pursuant to the terms of the Pfizer agreement on April 3, 2007.

During the nine months ended March 31, 2007, cash flows provided by financing activities consisted of the following transactions:

- (a) Share offerings:
 - In February 2007, we sold 50,044,132 units, each representing one ordinary share together with two four-year warrants to purchase an ordinary share at A\$0.23 per share for net proceeds of A\$10.8 million (\$8.5 million).
 - In December 2006, we sold 14,330,768 units, each representing one ordinary share together with two four-year warrants to purchase an ordinary share at A\$0.26 per share for net proceeds of A\$3.6 million (\$2.8 million).
- (b) Issuance of Absolute convertible notes:
 - In September 2006, we sold \$6.5 million principal amount of subordinated convertible notes net of issuance costs of \$1.1 million.
- (c) Amendments of Sandell convertible note:
 - In connection with the September 14, 2006 amendment of the Sandell convertible note we (i) repaid \$2.5 million of the note principal and (ii) made an additional payment to Sandell of \$1.0 million. In connection with that amendment and a subsequent letter agreement modification dated October 17, 2006, we incurred aggregate borrowing costs of \$670,000.

We had no borrowings or line of credit facilities as of March 31, 2008.

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 (including changes thereto), revenues, expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Contractual Obligations

The following table summarizes our minimum contractual obligations as of March 31, 2008 to make payments under existing operating leases and outstanding purchase obligations.

		Payments Due by Period				
Contractual Obligations	Total	Less than 1 year	1-3 years (In thousands)	3-5 years	More than 5 years	
Operating Lease Obligations	\$1,166	\$ 439	\$ 722	\$ 5	\$ —	
Purchase Obligations	420	413	7			
Total	\$1,586	\$ 852	\$ 729	<u>\$ 5</u>	<u>\$</u>	

Our purchase obligations consist primarily of purchase orders (i) for clinical trial materials, capital expenditures, supplies and other operating needs; and (ii) for commitments under contracts for maintenance needs and other services, including expansion of our BioSilicon manufacturing capacity. We excluded long-term agreements for services and operating needs that can be cancelled without penalty.

We also have contractual obligations that are variable in nature and, as such, are not included in the above table. These include the following:

Executive contracts. The Company has agreements with three executive officers which will require the Company to make severance payments to them if the Company terminates their employment without cause or the executives resign for good cause. If the Company terminated all three executives as of March 31, 2008, or if all three executives resigned for good cause on such date, the Company would be required to make aggregate payments up to approximately \$900,000 to these executives. The Company may also be required to make additional aggregate payments of up to \$800,000 to Dr. Ashton pursuant to a non-competition agreement. Payments under this non-competition agreement would be reduced on a dollar-for-dollar basis by any amounts paid to Dr. Ashton pursuant to the severance arrangements set forth in his employment agreement. The amounts payable to the Company's executives pursuant to severance arrangements change over time depending upon the date of termination and their then current salaries.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company will be required to implement SFAS 157 on July 1, 2008 and is currently assessing the impact of adoption.

In February 2007, the FASB issued SFAS No. 159 "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"), which permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007. The Company is currently evaluating the impact, if any, of SFAS 159 on its financial position, results of operations and cash flows.

In December 2007, the FASB issued SFAS No. 141 (revised), "Business Combinations" ("SFAS 141 (revised)"). SFAS 141 (revised) relates to business combinations and requires the acquirer to recognize the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date. SFAS 141 (revised) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. An entity may not apply it before that date. The Company must adopt this standard on a prospective basis for any business combinations entered into after June 30, 2009.

In December 2007, the FASB issued SFAS No. 160, "*Noncontrolling Interests in Consolidated Financial Statements*— *an amendment of Accounting Research Bulletin No.* 51" ("SFAS 160"), which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes reporting requirements that require sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective as of the beginning of an entity's fiscal year that begins after December 15, 2008, which will be our fiscal year beginning July 1, 2009. The Company is currently evaluating the impact, if any, of the adoption of SFAS 160 on its financial position, results of operations and cash flows.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities — an amendment of FASB Statement No. 133" ("SFAS 161"). FAS 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial performance, and cash flows. The guidance in SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. This Statement encourages, but does not require, comparative disclosures for earlier periods at initial adoption. The Company is currently assessing the impact of SFAS 161.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We have exposure to changes in foreign currency exchange rates, valuation of derivative liabilities and interest rates.

Foreign Currency Exchange Rates

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling. The U.S. dollar operates as the functional currency for our U.S. and Australian operations and the Pound Sterling as the functional currency for our U.K. operations. Cash to fund working capital requirements is managed centrally by the U.S. subsidiary. In connection with the ongoing consolidation of functions in the United States, cash and cash equivalents have become significantly concentrated in U.S. dollars.

At March 31, 2008, pSivida Limited had cash balances denominated in Australian dollars of A\$276,000. The following table shows the sensitivity of our consolidated statements of operations to an appreciation or depreciation in the value of the Australian dollar currency against pSivida Limited's U.S. dollar functional currency.

			Current			
A\$ Depreciation		A\$ Depreciation		A	\$ Apprecia	ion
-15%	-10%	-5%		+5%	+10%	+15%
		(In thou	isands of U.S	S. dollars)		
\$(38)	\$(25)	\$(13)		\$13	\$ 25	\$ 38
	-15%	<u>-15%</u> <u>-10%</u>	-15% -10% -5% (In thou	A\$ Depreciation Rate -15% -10% -5% (In thousands of U.S.)	A\$ Depreciation Rate A -15% -10% -5% +5% (In thousands of U.S. dollars)	A\$ Depreciation Rate A\$ Appreciation -15% -10% -5% +5% +10% (In thousands of U.S. dollars)

Derivative Liabilities

In connection with several capital raising transactions, we issued ordinary shares together with detachable warrants to purchase additional ordinary shares over a specified time period. Since these warrants were denominated in A\$, which is different than the Company's US\$ functional currency, the values of these warrants were recorded as derivative liabilities, subject to revaluation at subsequent reporting dates. The change in fair value of derivatives related to these investor warrants resulted in income of approximately \$1.2 million and \$7.2 million during the three and nine months ended March 31, 2008, respectively, and was determined using the Black-Scholes valuation model.

Our financial position and results of operations will be sensitive to future revaluations of these derivative liabilities. The primary factor that impacts the change in fair value of these derivatives is fluctuations in our share price. Reduction of the remaining useful life of the warrants, assuming that share price remains constant, will result in a modest decrease of the derivative liability value. Changes in risk-free interest rates have a deminimis effect.

At March 31, 2008, the closing price of the Company's ordinary shares traded on the ASX was A\$0.09 per share. The following table summarizes the sensitivity of our consolidated statements of operations for the three months ended March 31, 2008 to assumed increases or decreases of the Company's ASX share price at March 31, 2008:

			Current					
Decrea	Decrease in A\$ Stock Price		Decrease in A\$ Stock Price		Price	Increas	se in A\$ Stoc	k Price
-15%	-10%	-5%	· · · · · · · · · · · · · · · · · · ·	+5%	+10%	+15%		
(In thousands of U.S. dollars)								
\$ 636	\$ 433	\$ 221	\$ —	\$(230)	\$(468)	\$(715)		
	-15%	-15% -10%	-15% -10% -5% (In the	Decrease in A\$ Stock Price	Decrease in A\$ Stock Price Price Increase 15% -10% -5% +5% (In thousands of U.S. dollars)	Decrease in A\$ Stock Price Price Increase in A\$ Stock -15% -10% -5% +5% +10%		

Interest Rates

Cash and cash equivalent balances are subject to variable interest rates. We do not consider our exposure to interest rates to be significant.

Item 4. Controls and Procedures

Disclosure controls and procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective as of such date. The basis for this determination is that, as discussed below, we previously identified a material weakness in our internal control over financial reporting as part of management's assessment of the Company's internal control over financial reporting as of June 30, 2007. We regard our internal control over financial reporting as an integral part of our disclosure controls and procedures.

In connection with our management's assessment of our internal control over financial reporting as reported in our annual report on Form 20-F for the year ended June 30, 2007, the following material weakness was identified as of June 30, 2007 for which remediation is in process:

• A number of audit adjustments and additional disclosures have been made to the Company's 2007 consolidated financial statements, principally including an adjustment to allocate the loss on extinguishment of debt between liability and equity, a reclassification adjustment to record the change in fair value of derivative on redemption of convertible debt with a corresponding change in the loss on extinguishment, the reversal of an amount of revenue, and related adjustments to income tax benefit recorded. Management has determined that these adjustments and reclassifications resulted from the control deficiency that there is an inadequate amount of accounting and finance personnel sufficiently trained to address certain of the major transactions and complex accounting and financial reporting matters that arise from time-to-time and that this control deficiency constitutes a material weakness.

Changes in internal control over financial reporting

In our annual report on Form 20-F for the year ended June 30, 2007, we identified the material weakness in our internal control over financial reporting set forth in the paragraph above. During the three months ended March 31, 2008, we implemented the following actions for purposes of complying with Section 404 of the Sarbanes-Oxley Act of 2002:

- As of March 31, 2008, we have completed the process of hiring the accounting and finance personnel and outside consultants needed to address the material weakness in internal control over financial reporting identified in our annual report on Form 20-F for the year ended June 30, 2007.
- We made preparations to reincorporate in the United States. Reincorporation in the United States would simplify our regulatory compliance
 obligations and make available to us more resources for resolving US GAAP accounting issues, as we would no longer be required to prepare
 financial statements in accordance with A-IFRS. The reincorporation is subject to Australian Federal Court and shareholder approval.

Other than those changes referenced above, there have been no other changes in our internal control over financial reporting during the period covered by this quarterly report that have materially affected, or are reasonably likely to affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in Part I, "Item 3.D. Risk Factors" of our Annual Report on Form 20-F for the fiscal year ended June 30, 2007, except as follows.

Risks related to our company and our business

The risk factor entitled "Our ability to obtain additional capital is uncertain, and if we do not obtain it, we may not be able to fund our operations and the development of our products and may be required to suspend, curtail or terminate our operations" is deleted.

The following risk factors are added, and the risk factor entitled "Our current licensees may terminate their agreements with us at any time, and if they do, we may not be able to effectively develop and sell our products" is modified as set forth below.

If we do not receive expected payments from Pfizer or Alimera, we may be required to seek additional capital in order to fund our operations, and our ability to obtain additional capital is uncertain.

Our cash and cash equivalents totaled approximately \$18.2 million at March 31, 2008. We currently believe that if the Pfizer and Alimera agreements continue and we receive the Pfizer research and development funding, Alimera continues to fund the development of Medidur FA and we receive the scheduled conditional note payments from Alimera, our existing cash resources together with these payments will be sufficient to fund our operations under our current operating plan through at least June 30, 2010. However, if Pfizer or Alimera fails to make these expected payments or if Alimera stops funding the development of Medidur FA, we may be required to seek additional capital prior to June 30, 2010. Whether and when we will require additional capital will depend upon many other factors, including, but not limited to:

- the continuation of and payments under, our existing collaboration and license agreements with Pfizer, Alimera and others, including their continued
 funding of our programs and our receipt of milestone, royalty, note and other payments, and the development of new collaboration and licensing
 agreements for other product candidates, such as BrachySil;
- the amount and timing of sales of Retisert, which affects the timing of resumption of Retisert royalty payments and the amount of such royalty payments;
- · the scope and extent of our internally funded operations, including our programs for BrachySil and other BioSilicon product candidates;
- our ability to establish and maintain strategic arrangements (in addition to those set forth above) for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates including the timing and costs of regulatory approvals and the commercial success of approved products:
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- changes in our current operating plan, which may affect our need for capital; and
- the consummation of our proposed reincorporation.

If we require additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potentially dilutive equity, and collaboration agreements may be on unfavorable terms including requiring us to relinquish rights to our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or otherwise reduce our cash requirements.

Our current licensees may terminate their agreements with us at any time, and if they do, we may not be able to effectively develop and sell our products.

Our licensees have rights of termination under our agreements with them. Exercise of termination rights by those parties may leave us temporarily or permanently without development, 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 that could compete with our products. Further, disagreements over rights or technologies or other proprietary interests may occur.

We have exclusively licensed certain of our controlled drug delivery technologies to Pfizer for ophthalmic applications. Pfizer is funding research and further development and commercialization of products licensed under our agreement with them. Pfizer may terminate the agreement at any time and for any reason upon 60 days written notice. We have exclusively licensed our technology with respect to Vitrasert, Retisert and certain other ophthalmic uses to Bausch & Lomb, and with respect to Medidur for DME and certain other ophthalmic uses to Alimera Sciences. Bausch & Lomb is responsible for funding and managing the development and commercialization of all licensed products and can terminate its agreement with us at any time upon 90 days' written notice. Pursuant to the amended collaboration agreement with Alimera, Alimera has assumed financial responsibility for the development of licensed products, along with sole responsibility for the commercialization of such licensed products. Alimera may abandon the development and commercialization of any licensed product at any time.

Alimera was incorporated in June 2003 and has limited resources. Any of Pfizer, Bausch & Lomb or Alimera 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 us. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance as to whether, and to what extent, that experience and those resources will be devoted to our technologies. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize these products and proposed products, decisions, actions, breach or termination of these agreements by Pfizer, Bausch & Lomb or Alimera could delay or stop the development or commercialization of Retisert, Medidur for DME or other of our products licensed to such entities.

If our proposed reincorporation in the United States is not implemented, our independent auditor may resign, and we may be unable to engage a replacement independent auditor.

Primarily because we are incorporated in Australia whilst most of our assets and operations are located in the United States and because we are now required to file annual audited and interim unaudited financial reports in the United States in compliance with US auditing standards in addition to in compliance with Australian securities regulation, our independent auditor has indicated that, unless the reincorporation is approved, it will seek the consent of the Australian Securities and Investment Commission to resign as our Australian statutory auditor at the 2008 annual general meeting and could earlier cease its role with respect to our US reporting and auditing requirements.

If we are not reincorporated and our independent auditor resigns, we believe that it would be difficult to engage a replacement independent auditor because any potential replacement independent auditor would likely assess us as a client in substantially the same manner as our current independent auditor. In particular, we believe that it would be difficult to engage a replacement independent auditor because: (i) we are currently required to have our financial statements audited both in accordance with A-IFRS presented in A\$ and in accordance with US GAAP presented in US\$; (ii) substantially all of our assets and operations are located outside of Australia while we are incorporated in Australia; and (iii) we are regulated as a domestic issuer under both Australian and US securities laws and under ASX and NASDAQ rules. Under applicable laws and listing requirements, our annual financial statements must be audited, and our interim unaudited financial statements must be reviewed, by an independent auditor. Therefore, unless the reincorporation is approved, we could be unable to meet these requirements, beginning with our financial statements for the quarter ending September 30, 2008. If we cannot issue our financial statements on a timely basis, we will violate regulatory requirements and ultimately be delisted from ASX, NASDAQ and the Frankfurt Stock Exchange, and will breach contractual agreements related to its outstanding registration statements for the issuance and resale of securities, resulting in potentially significant cash penalties.

Risks related to our stock and our ADSs

The following additional risk factor now forms part of the risk factors.

The liquidity and price of our ADSs may be negatively impacted if they are delisted from NASDAQ.

Our ADSs are currently listed for trading on the NASDAQ Global Market. We must continue to satisfy NASDAQ's continued listing requirements, including maintaining a minimum bid price for our ADSs of \$1.00 per ADS, or risk delisting which could have a material adverse affect on our business. A delisting of our ADSs from NASDAQ could materially reduce the liquidity of our ADSs and result in a corresponding material reduction in the price of our ADSs. In addition, any such delisting could harm our ability to raise capital on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees.

In December 2007, we received a letter from the NASDAQ Listing Qualifications Department notifying us that, for the prior 30 consecutive business days, the bid price of our ADSs had closed below the minimum \$1.00 per share required for continued listing on the NASDAQ Global Market. Under the rules set forth by the NASDAQ Listing Qualifications Department, issuing this notice is customary practice when a NASDAQ quoted company's closing bid price has been less than \$1.00 per share for 30 consecutive trading days. NASDAQ has provided us with a grace period of 180 calendar days, or until June 24, 2008, to regain compliance. In order to regain compliance, the bid price of our securities must close at \$1.00 per share or more for a minimum of ten consecutive trading days.

The share exchange contemplated as part of the proposed reincorporation transaction is expected to assist in satisfying the minimum bid price requirement; however, we cannot predict what the actual trading price of our securities will be after the reincorporation. If we do not regain compliance with the \$1.00 minimum bid price requirement by June 24, 2008, NASDAQ will provide written notice that our securities will be delisted from the NASDAQ Global Market. At that time, we may appeal NASDAQ's determination or we may apply to transfer our securities to the NASDAQ Capital Market. In the event that our securities appear likely to be delisted from the NASDAQ Global Market, we expect that, upon application thereto, our securities would then trade on the NASDAQ Capital Market, where we will have 180 days to regain compliance with the NASDAQ minimum bid price requirements. If the reincorporation is not implemented or is not implemented on a schedule that would permit our securities to trade on NASDAQ for ten trading days following the reincorporation by June 24, 2008, our ability to regain compliance is uncertain.

Item 5. Other Information

(a). As a result of the Company's decision to seek to reincorporate in the United States, the Company determined to continue Aaron Finlay's role on a consultancy basis. Accordingly, the Company entered into a contractor agreement dated February 29, 2008 with Sol Capital Pty Ltd, a company wholly owned by Mr. Finlay, to formalize the consultancy arrangement. The Company agreed to pay Mr. Finlay, through Sol Capital Pty Ltd, a gross monthly fee of A\$13,000. In return, Mr. Finlay will provide the Company with such services as are agreed from time to time as relevant to the Company's operations and that are within the scope of Mr. Finlay's expertise. Mr. Finlay will provide such services for a maximum of two days per week. The Company may also request Mr. Finlay to work additional hours at a gross rate of A\$240 per hour. The term of the agreement is six months from February 29, 2008. The Company and Aaron Finlay also entered into a Deed of Release dated February 29, 2008 pursuant to which Aaron Finlay agreed to resign, effective February 28, 2008, as Company Secretary and from his positions at pSiNutria Limited. The Company agreed to pay Mr. Finlay an aggregate gross amount of A\$177,019 under this Deed of Release. The Company also agreed that Mr. Finlay may exercise any options in the Company held by or behalf of Mr. Finlay that vest prior to December 31, 2010 until such options expire or are exercised. All unvested options in the Company held by Mr. Finlay on January 1, 2011 will automatically be cancelled by the Company. Mr. Finlay agreed to release the Company from all claims arising out of his positions with the Company and his resignation. The Company agreed to a limited release of Mr. Finlay.

Item 6. Exhibits

- (a) Exhibits
- 10.1 Amended and Restated Collaboration Agreement by and between pSivida Inc. and Alimera Sciences, Inc. dated March 14, 2008 (i)
- 10.2 Deed of Release between pSivida Limited and Aaron Finlay, dated February 29, 2008 (ii)
- 10.3 Contractor Agreement between pSivida Limited and Sol Capital Pty Ltd February 29, 2008 (ii)
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- (i) Filed herewith (Subject to a previously filed request for confidential treatment)
- (ii) Filed herewith

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Incorporation by Reference

pSivida Limited hereby incorporates by reference this Quarterly Report on Form 10-Q, other than Exhibits 32.1 and 32.2 hereto, in the Company's registration statements (Nos. 333-132776, 333-132777, 333-135428, 333-141083, 333-141091 and 333-143225) on Form F-3.

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SIGNATURES

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

pSivida Limited (Registrant)

Date: May 12, 2008 By: /s/ Paul Ashton

Name: Paul Ashton
Title: Managing Director

Date: May 12, 2008 By: /s/ Michael J. Soja

Name: Michael J. Soja

Title: Vice President, Finance and Chief Financial Officer

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Revised Execution Version

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

AMENDED AND RESTATED

COLLABORATION AGREEMENT

BY AND BETWEEN

PSIVIDA, INC. (f/k/a CONTROL DELIVERY SYSTEMS, INC.)

AND

ALIMERA SCIENCES, INC.

DATED AS OF MARCH 14, 2008

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AMENDED AND RESTATED COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED COLLABORATION AGREEMENT (the "<u>Agreement</u>") dated as of March 14, 2008 (the "<u>Amendment Effective Date</u>"), is made by and between PSIVIDA, INC. (f/k/a 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 ("<u>CDS</u>"), 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 ("<u>Alimera</u>"). 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 were 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 was willing to grant Alimera a license to certain of its proprietary technology and know-how relating to developing products for treating eye diseases; and

WHEREAS, the Parties entered into such a collaboration and licensing relationship upon the terms and conditions set forth in the Collaboration Agreement by and between Control Delivery Systems, Inc. and Alimera Sciences, Inc. (the "Original Agreement") dated as of February 11, 2005 (the "Effective Date"), as amended by Amendment No. 1 dated February 23, 2005 and Amendment No. 2 dated May 11, 2005; and

WHEREAS, CDS and Alimera desire to enter into this Agreement to amend and restate the Original Agreement (as amended prior to the Amendment Effective Date) as of the Amendment Effective Date as set forth herein;

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.

- 1.1A "Alimera Development Activities" shall mean (a) for activities conducted prior to the Amendment Effective Date, Alimera's development activities conducted as set forth in the Development Plan (as defined in the Original Agreement) and (b) for activities conducted on and after the Amendment Effective Date, all Alimera development activities related to this Agreement.
- 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) 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.
 - 1.3A "Alimera Note" shall have the meaning set forth in Section 6.2A.
- 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.
 - 1.4A "AMD" means age-related macular degeneration.
 - 1.4B "Amendment Effective Date" shall have the meaning set forth in the preamble.
- 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).
- 1.10A "CDS Development Activities" shall mean (a) for activities conducted prior to the Amendment Effective Date, CDS' development activities conducted as set forth in the Development Plan (as defined in the Original Agreement) and (b) for activities conducted on and after the Amendment Effective Date, CDS' development activities conducted to the extent specifically set forth in Section 3.1.2 herein.
- 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 CDS Development Activities, that are (a) Improvements covered by or derived from practice of the CDS Technology, and/or (b) Improvements covered by or derived from the practice of the Improvements 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 <u>Exhibit 1.15</u>.
- 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 (as all defined in the Original Agreement), (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 (as both defined in the Original Agreement), 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 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, pursuant to the Development Activities. For the avoidance of doubt, supplies for Non-NDA Trials are excluded from the definition of Clinical Supply Requirements.
- 1.24 "CODRUG™" 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™ 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 [*] 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 Intentionally omitted.
 - 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 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.
 - 1.33A "Development Activities" shall mean the Alimera Development Activities and CDS Development Activities.

- 1.34 Intentionally omitted.
- 1.35 Intentionally omitted.
- 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);
- (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 both activities under the Commercialization Budget and Development Activities, 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. Notwithstanding anything else herein, no Direct Development Costs may be categorized as Direct Commercialization Costs.

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 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:
- (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, 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 Activities (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 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 and part of Development Activities; and
 - (h) Other Direct Costs as mutually agreed upon by the Parties.

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 Development Activities 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 both activities under the Commercialization Budget and Development Activities, 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 have the meaning set forth in the recitals.
- 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.
 - 1.43A "Fifty/Fifty Amendments" shall mean both of the following amendments:
- (1) In the first sentence of Section 6.5.1, the words "Alimera and CDS shall be entitled to eighty percent (80%) and twenty percent (20%), respectively," shall be deleted and the words "each Party shall be entitled to fifty percent (50%)" shall be substituted in their place.
- (2) In Section 6.6, the words "twenty percent (20%)" shall be deleted and the words "fifty percent (50%)" shall be substituted in their place, and the words "thirty-three percent (33%)" shall be deleted and the words "fifty percent (50%)" shall be substituted in their place.
- 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 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 Intentionally omitted.
- 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 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.
 - 1.55A "Medidur FA" shall mean the product being developed as of the Amendment Effective Date under IND #72056.
 - 1.56 "Milestone Payments" 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
 - (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, (ii) post-Approval or post-marketing trials required by the FDA or other regulatory authority in granting a conditional Approval, or (iii) trials required to obtain Approval for pediatric use of a Product, whether such trials are prior or subsequent to the filing of an NDA or Approval.
 - 1.62 Intentionally omitted.
- 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.
 - 1.65A "Original Agreement" shall have the meaning set forth in the recitals.
 - 1.66 Intentionally omitted.
 - 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.
- 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 Intentionally omitted.
- 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™ and no other active ingredient, where the core does not include a CODRUG™, (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. The Parties acknowledge that Medidur FA is a First Product.

- 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 [*] 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 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 he 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, 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 E

- 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 <u>Exhibit 1.87</u>, 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 Intentionally omitted

ARTICLE 3 DEVELOPMENT ACTIVITIES

- 3.1 <u>General</u>. Subject to Sections 3.1.1 and 3.1.2 below, (a) CDS and Alimera shall undertake development activities for the Products in the Collaboration Field in accordance with this Agreement and (b) during the course of performing such activities, 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 this Agreement.
- 3.1.1. <u>Limitation on CDS Development</u>. Notwithstanding any other provision in this Agreement to the contrary (including any provision of Article 2 or 3) and except as the Parties mutually agree in writing, CDS will have no obligation relating to the development of (a) Medidur FA after December 31, 2009 or (b) any Product other than Medidur FA at any time on or after the Amendment Effective Date.
- 3.1.2. CDS Development Responsibilities and Development Payments. Subject to Section 3.1.1 and this Section 3.1.2, CDS shall be responsible for the performance of only the following development activities: (a) providing clinical supply of Medidur FA as necessary for: (i) the FAME trial (i.e., the fluocinolone acetonide in macular edema trial) ongoing as of the Amendment Effective Date to the extent set forth in protocol C-01-05-001 under IND # 72056, (ii) the PK trial ongoing as of the Amendment Effective Date to the extent set forth in protocol C-01-06-002 under IND # 72056, (iii) an upcoming wet AMD trial for up to thirty (30) patients, (iv) an upcoming vein occlusion trial for up to thirty (30) patients, and (v) one additional marketing support trial, similar to the wet AMD and vein occlusion trials, for up to thirty (30) patients; (b) with respect to Medidur FA, performing the support expressly set forth on Exhibit 3.1.2A hereto for: (i) stability studies for clinical supply of Medidur FA, and (ii) ongoing preclinical work; and (c) performing the technology transfer activities with respect to Medidur FA set forth in Section 3.11. CDS will be reimbursed by Alimera for the costs associated with CDS Development Activities pursuant to this Section 3.1.2, and such payments shall be deemed Direct Development Costs, provided that all such reimbursed costs associated with the wet AMD trial, the vein occlusion trial and the additional marketing support trial shall be deemed Direct Commercialization Costs to the extent such trials are Non-NDA Trials.

CDS Development Budget. Attached hereto as Exhibit 3.1.2B as of the Amendment Effective Date is CDS' initial budget relating to CDS Development Activities (the "CDS Development Budget"). CDS shall from time to time provide to Alimera an updated written budget relating to CDS Development Activities promptly after CDS becomes aware of any discrepancy between the cost of

performing the CDS Development Activities and the amount included in the current CDS Development Budget, which updated budget will become the new "CDS Development Budget" hereunder following good faith discussions and agreement by the Parties in writing on the content thereof.

CDS Reporting and Reimbursement. During the course of the CDS Development Activities as described in this Section 3.1.2, within fifteen (15) calendar days after the end of each calendar month, CDS shall report in writing to Alimera a detailed itemization (including copies of any third party invoices) of the actual costs incurred by CDS in the preceding calendar month. Alimera shall reimburse CDS the actual costs on a monthly basis as follows: to the extent CDS incurred such costs in a calendar month that are within (and do not exceed) the costs in the applicable CDS Development Budget, CDS shall issue an invoice to Alimera for the full amount of such costs incurred and Alimera shall pay to CDS the amount of such invoice (the "Development Payment") within thirty (30) calendar days after delivery of the invoice.

Non-Payment by Alimera. In the event that (i) Alimera fails to make a timely payment of all or a portion of any of its Development Payments and (ii) Alimera fails to pay all such payments under this Agreement within thirty (30) days after receiving written notice from CDS of such outstanding payments (provided that Alimera has a one-time right to use sixty (60) days to cure hereunder), then, automatically and without further action by CDS or Alimera, the Fifty/Fifty Amendments shall be deemed to have been made, which amendments shall apply to all payments due or paid thereafter. The foregoing states the entire liability of Alimera with respect to its failure to make a timely payment of all or a portion of any of its Development Payments (but will not limit Alimera's liability for any failure to pay CDS Net Profits payments, which is addressed in Section 6.5.1(c)(I)).

3.1.3. <u>Alimera Development Responsibilities</u>. Alimera shall use Commercially Reasonable Efforts to develop the First Product for at least one indication in the Collaboration Field. Before January 31st of each calendar year, Alimera shall provide CDS with a written status update of its Alimera Development Activities. Alimera shall have sole decision-making authority with respect to the development of Products, consistent with its other obligations under this Agreement.

3.2 Regulatory Approvals.

3.2.1. <u>Regulatory Filings</u>. Unless otherwise agreed in writing 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 sole authority and responsibility, for submitting supplements, communications, annual reports, adverse event reports, manufacturing changes, supplier designations and other related filings to, and for communicating with, the FDA and other regulatory authorities. Alimera shall provide CDS with copies of all substantive submissions to (which may be in draft form), and all correspondences from, the FDA or other regulatory authorities which relate to Products.

- 3.2.2. <u>Manufacture-related Activities</u>. 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. Alimera shall have the right to inspect and audit CDS' manufacturing facility and related records and its operations, in each case solely to the extent related to Medidur FA, upon reasonable notice. Any information obtained by Alimera during such visits shall be treated as Confidential Information in accordance with Article 8 of this Agreement.
- 3.2.3. <u>Documentation</u>. 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. Alimera shall provide a copy of all such records to CDS within ten (10) Business Days of reasonable request by CDS. Within ninety (90) days after the Amendment Effective Date, CDS shall provide a copy of all such records that relate to Medidur FA to Alimera (to the extent such records have not previously been provided by CDS to Alimera). In addition, within thirty (30) days after the end of each calendar quarter following the Amendment Effective Date, CDS shall provide to Alimera a copy of all such records that relate to Medidur FA and were generated during such calendar quarter. Without limiting any other provision of this Agreement, upon at least ten (10) days prior written notice, during regular business hours, 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 for Medidur FA in the Territory.
- 3.2.4. 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 with respect to any Product; 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 with respect to any Product.
- 3.2.5. Meetings. In connection with Sections 3.2.1 through 3.2.4 above, Alimera shall provide CDS 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 Medidur FA) scheduled with FDA or such other regulatory authorities concerning any regulatory matters relating to the Product within five (5) days after Alimera receives notice of the scheduling of such meetings, conferences, or discussions.

3.3 Performance.

3.3.1. <u>Commercially Reasonable Efforts</u>. Subject to Section 3.1.1 and 3.1.2, each Party shall use Commercially Reasonable Efforts to conduct all development activities and responsibilities assigned to it under this Agreement.

3.3.2. Intentionally omitted.

- 3.4 <u>Primary Contact Persons</u>. As of the Amendment Effective Date, CDS has designated [*] as CDS' primary contact person and Alimera has designated [*] as Alimera's primary contact person (each, a "<u>Primary Contact Person</u>"). The Primary Contact Persons shall be responsible for the day-to-day interactions between the Parties related to Development Activities 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 performing such activities. 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 resolved in accordance with Section 12.7. Each Party may change its Primary Contact Person upon written notice to the other Party.
- 3.5 <u>Availability of Employees</u>. Each Party agrees to make its employees involved in the conduct of the Development Activities related to Medidur FA reasonably available upon reasonable advance notice and during business hours at their respective places of employment to consult with the other Party on issues related to Medidur FA, including, but not limited to, regulatory, scientific, technical and clinical testing issues, arising under Development Activities and in connection with any request from any regulatory agency.
- 3.6 <u>Visit of Facilities</u>. 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 in connection with Medidur FA. 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 <u>Subcontracts</u>. 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, provided that CDS shall obtain the prior written consent of Alimera to subcontract its development activities, which consent shall not be unreasonably withheld or delayed (each such subcontractor, a "<u>Permitted Subcontractor</u>"). Any subcontract entered into pursuant to this Section 3.7 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.
- 3.8 <u>Information Sharing</u>. Each Party shall provide the other Party with such information related to the providing Party's Development Activities as the other Party may reasonably request.

- 3.9 Records. The Parties will make available to one another all results of the work conducted pursuant to the Development Activities, will promptly disclose to one another such results to the extent they are material, 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 (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. 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 clinical supply, but limited to such quantities and such type and specification as set forth in Section 3.1.2 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 reimbursed by Alimera in accordance with Section 3.1.2 and shall be Direct Development Costs (except that the Manufacturing Costs associated with the wet AMD trial, the vein occlusion trial and the additional marketing support trial shall be deemed Direct Commercialization Costs to the extent such trials are Non-NDA Trials). All Clinical Supply Requirements (beyond those listed in Section 3.1.2) will be Alimera's sole responsibility.
- 3.11 Technology Transfer by CDS. Upon the earlier of: (i) written request by Alimera to CDS and (ii) [*] prior to [*], CDS and/or its Permitted Subcontractors shall be responsible for providing to Alimera all information, support and materials that are in each case in CDS' Control and reasonably necessary to enable Alimera and/or its subcontractors to manufacture and perform quality testing on Medidur FA to satisfy Commercial Supply Requirements, all to the extent set forth in the CDS Development Budget and reimbursed pursuant to Section 3.1.2. CDS and/or its Permitted Subcontractors shall be responsible for the following activities in association therewith (to the extent set forth in the CDS Development Budget and any costs of which will be reimbursed by Alimera in accordance with Section 3.1.2): (a) assist with technology transfer to commercial manufacture site, (b) assist with manufacturing scale-up and validation activities, and (c) transfer analytical methods to commercial manufacture site for stability monitoring. In addition, within ninety (90) days after the Amendment Effective Date, CDS shall provide to Alimera a Pharmaceutical Development

Report, the form and content of which should follow the ICH Guidance documents Q8 Pharmaceutical Development (dated May 19, 2006) and draft Q8(R1) Pharmaceutical Development Revision 1 (dated January 10, 2008). Within thirty (30) days after receipt of such report, Alimera shall notify CDS in writing whether such report is accepted or rejected (provided that any rejection must be reasonable). If Alimera notifies CDS of its acceptance or fails to notify CDS of its reasonable rejection within the thirty (30) day time period, then such report is deemed to be accepted. If Alimera reasonably rejects the report, then it shall notify CDS in writing of its reasons, with reasonable specificity, for the rejection, and CDS shall use commercially reasonable efforts to revise the report to address such reasons within ten (10) Business Days following receipt of such rejection notice and reasons. CDS shall submit the revised report to Alimera for another review in accordance with the acceptance procedures and timeline specified above. 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 <u>Commercialization of Product(s) in the Collaboration Field</u>. 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. Alimera shall have sole decision-making authority with respect to the Commercialization of Products, consistent with its other obligations under this Agreement.
- 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") that 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 updated Commercialization Budget due by December 31, 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 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 Alimera shall have sole decision-making authority with respect to the Commercialization Budget, consistent with its other obligations under this Agreement. Alimera shall provide an initial draft Commercialization Budget to CDS on the Amendment Effective Date.

- 4.3 <u>Diligence</u>. Alimera shall use Commercially Reasonable Efforts to Commercialize the First Product for at least one indication in the Collaboration Field in [*] (collectively, the "<u>Major Markets</u>") 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 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 the Alimera First Products in the United States during the [*] period referred to in Section 4.3.4 to be at least [*] more than Gross Sales of the Alimera First Products in the United States during the immediately preceding [*] period. Alimera's 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: [*].

4.3.8. Non-Performance.

- (a) In the event the Fifty/Fifty Amendments have not previously been made in accordance with Sections 3.1.2, 4.3.8(a), 4.4, 6.2B or 6.5.1(c)(II),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 (provided that Alimera has a one-time right to use sixty (60) days to cure hereunder), then, automatically and without further action by CDS or Alimera, the Fifty/Fifty Amendments shall be deemed to have been made, which amendments shall apply to all payments due or paid thereafter.
- (b) In the event the Fifty/Fifty Amendments have previously been made in accordance with Sections 3.1.2, 4.3.8(a), 4.4, 6.2B or 6.5.1(c)(II), 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 (provided that Alimera has a one-time right to use sixty (60) days to cure hereunder), 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 [*]. 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 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.
- 4.3.10 The Parties acknowledge and agree that Alimera's obligations in Sections 4.3.1 through 4.3.5 reflect the Parties' assumption that the first First Product Approval in the United States will be for DME or AMD. If at any time a Phase III Clinical Trial is initiated with respect to the First Product for an indication other than DME or AMD prior to the Approval of the First Product for DME or AMD, then the Parties will discuss in good faith Alimera obligations paralleling those in Sections 4.3.1 through 4.3.5 with respect to such non-DME and non-AMD First Product (should it then be Approved). If such non-DME and non-AMD First Product is then Approved before the First Product for DME or AMD is Approved, the portions of such obligations paralleling Sections 4.3.2 through 4.3.4 that are agreed-upon by the parties with respect to such non-DME and non-AMD First Product will be deemed subtracted from the numbers set forth in Sections 4.3.2 through 4.3.4, respectively, with respect to the First Product for DME or AMD to be Approved (the intent of the Parties being that Alimera will not be obligated to spend more than the amounts set forth as of the Amendment Effective Date in such Sections cumulatively for the two Products discussed above).
- 4.4 <u>Costs of Commercialization</u>. 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 [*] and that the reimbursement percentage for the amount described in clause (a) may be less than [*] to the extent provided in Section 7.1.2. 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 (i) Alimera fails to reimburse CDS within the time period specified above, and (ii) Alimera fails to pay all such payments under this Agreement within thirty (30) days after receiving written notice from CDS of such outstanding payments (provided that Alimera has a one-time right to use sixty (60) days to cure hereunder), then, automatically and without further action by CDS or Alimera, the Fifty/Fifty Amendments shall be deemed to have been made, which amendments shall apply to all payments due or paid thereafter. The foregoing states the entire liability of Alimera with respect to its failure to make a timely payment of all or a portion of any of its CDS Commercialization Costs (but will not limit Alimera's liability for any failure to pay CDS Net Profits payments, which is addressed in Section 6.5.1(c)(I)).

- 4.5 <u>Manufacturing for Commercial Supply Requirements</u>. 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 <u>Product Recalls</u>. 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 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. <u>License to First Product</u>. 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 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 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 [*], 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 <u>License to Exhibit 1.11B Patents</u>. Subject to the terms and conditions of this Agreement and only to the extent permitted by the B&L Agreement, CDS hereby grants to 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 <u>Exhibit 1.11B</u>, 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 <u>Grant of License by Alimera</u>. 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 performance of the CDS Development Activities.

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 or subcontracts to which any Alimera Affiliate is a party or which include Bundling (as defined below), Alimera shall obtain CDS' prior written consent, which consent shall not be unreasonably withheld or delayed. For the purposes of this Section 5.3, "Bundling" is a situation in which all three of the following exist: (i) the offering (whether simultaneously or not) by Alimera or its Affiliates to a Third Party, or by a Third Party to Alimera or its Affiliates, of any rights, goods or services with respect to a Product (including sale of Product itself); (ii) the offering (whether simultaneously or not) by Alimera or its Affiliates to a Third Party, or by a Third Party to Alimera or its Affiliates, of any other rights, goods or services (including any rights, goods or services relating to other products Alimera or any of its Affiliates Controls, sells or otherwise disposes of); and (iii) the consideration for the rights, goods or services with respect to any Product in such offering is less than would have been customarily accepted by Alimera, or more than would have been customarily provided by Alimera, if such rights, goods or services with respect to such Product were offered individually (i.e., separate from the bundle). 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 of the following sublicenses or subcontracts promptly after its execution: (i) those for which CDS' consent is required by this paragraph, (ii) those under which any rights are sublicensed, and (iii) those under which consideration owed by Alimera exceeds \$250,000; 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, if 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 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 <u>Limitation on Use</u>. 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, 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 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 Commercialize the Option Product on the same terms as the Original 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. <u>Cooperation</u>. 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 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 <u>License Fee.</u> The [*] in principal plus all accrued interest due under the Earnest Money Loan shall be treated as paid in full as the payment of a license fee, and the security interest under the Security Agreement (the "<u>Security Agreement</u>") 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 termination pursuant to Section 4 of the Security Agreement.

- 6.2 Milestone Payments. Alimera shall make the following additional payments to CDS ("Milestone Payments"):
- (a) An additional payment of [*] upon [*]. For purposes of this Section 6.2, the Parties agree that [*]. CDS acknowledges and agrees that it has received such [*] payment from Alimera, and that Alimera has no further obligations under this Section 6.2(a); and
 - (b) An additional payment of \$25,000,000 within 30 days after Approval by the FDA of the first First Product Approved by the FDA.
 - 6.2A Payments on Execution of Amended and Restated Agreement. On the Amendment Effective Date, Alimera will:
 - (a) Make a payment to CDS of \$12,000,000 in cash; and
 - (b) Issue a note in the principal amount of \$15,000,000 to CDS in the form of Exhibit 6.2A hereto (the "Alimera Note").
- 6.2B <u>Certain Alimera Note Payments and Events</u>. Upon any Interest Payment Default or Scheduled Payment Default pursuant to and as defined in the Alimera Note, then, automatically and without further action by CDS or Alimera, the Fifty/Fifty Amendments shall be deemed to have been made, which amendments shall apply to all payments due or paid thereafter.
- 6.3 <u>Development Costs</u>. With respect to activities prior to the Amendment Effective Date, each Party was to pay [*] of the total Direct Development Costs of a Product incurred in accordance with the Development Budget (as defined in the Original Agreement). Notwithstanding anything in this Article 6 of this Agreement or in any other provision of this Agreement to the contrary, with respect to activities on and after the Amendment Effective Date, subject to Sections 3.1.2, Alimera will be solely responsible for, and shall pay one hundred percent (100%) of, all development costs of a Product, including Direct Development Costs. Notwithstanding anything in this Article 6 of this Agreement or in any other provision of this Agreement to the contrary, (i) all payments owing by CDS hereunder with respect to development activities prior to the Amendment Effective Date are hereby deemed fully paid by CDS (or waived, to the extent such waiver may be required), including any Development Payments, Compounded Development Payments, Determined Disputed Costs and Compounded Disputed Costs (as all defined in the Original Agreement), further including any penalties and interest which might have accrued with respect thereto, and further including all CDS payments deferred pursuant to that February 11, 2008 letter agreement sent by CDS and executed by CDS and Alimera regarding deferral of payments under the Original Agreement as of such date; (ii) all payments owing by Alimera hereunder with respect to development activities prior to the Amendment Effective Date are hereby deemed fully paid by Alimera (or waived, to the extent such waiver may be required), including any Development Payments, Compounded Development Payments, Determined Disputed Costs and Compounded Disputed

Costs (as all defined in the Original Agreement), and further including any penalties and interest which might have accrued with respect thereto; and (iii) subject to Sections 3.1.1 and 3.1.2, from and after the Amendment Effective Date, CDS will have no liability whatsoever hereunder for any past, present or future development costs, including Direct Development Costs (which includes those incurred before, on and after the Amendment Effective Date), and instead Alimera shall have sole liability therefor.

- 6.3.1. Intentionally omitted.
- 6.3.2. Intentionally omitted.
- 6.3.3. Intentionally omitted.
- 6.4 <u>Revenues Prior to Profitability Date</u>. 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, Alimera and CDS shall be entitled to eighty percent (80%) and twenty percent (20%), respectively, 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.
- (a) <u>Reporting; Reconciliation of Net Profits.</u> 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);
 - (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 twenty percent (20%) 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 twenty percent (20%) of the amount of Net Profits Payment to which CDS is otherwise entitled for such calendar quarter until twenty percent (20%) 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 twenty percent (20%) 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 twenty percent (20%) 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 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 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 Products, 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.

- (I) In the event the Fifty/Fifty Amendments have previously been made in accordance with Sections 3.1.2, 4.3.8(a), 4.4, 6.2B or 6.5.1(c)(II), then 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 and does not cure such failure within thirty (30) days of receiving a written notice from CDS requesting Alimera to cure such failure, then CDS may exercise its rights pursuant to Section 11.2 of this Agreement; and
- (II) In all cases other than as described in provision (I) above, 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 thirty (30) days in which to cure the nonpayment (provided that Alimera has a one-time right to use sixty (60) days to cure hereunder). If after such notice, Alimera fails to cure the nonpayment within the cure period, then, automatically and without further action by CDS or Alimera, the Fifty/Fifty Amendments shall be deemed to have been made, which amendments shall apply to all payments due or paid thereafter.
- (d) <u>Consideration for Net Profits Payments</u>. 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. For the sake of clarity, the Parties have agreed not to decrease the percentage of Net Profits to be paid by Alimera to CDS, even if the Product is no longer covered by a Valid Claim in the CDS Patent Rights, in view of substantial CDS Know-How provided in the development of Product. Moreover, the Net Profits value itself will at all times reflect the then-current value of the intellectual property licensed hereunder and will naturally reflect any loss of the CDS Patent Rights.

6.5.2. <u>Net Losses</u>. 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 twenty percent (20%) 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, (A) with respect to all royalties received by Alimera thereunder, CDS shall be entitled to receive twenty percent (20%) of the amount of such royalties remaining after deduction of Direct Commercialization Costs incurred by Alimera in supporting the sublicense under which such royalties were received, and (B) with respect to all consideration received by Alimera thereunder other than royalties, CDS shall be entitled to receive thirty-three percent (33%) of the excess of (i) such non-royalty 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 acting in good faith, 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.

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 (including Development Payments), 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 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, 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 Alimera shall reimburse CDS fifty percent (50%) (subject to the last sentence of this paragraph) for all such costs paid by CDS within thirty (30) days after the date of invoice by CDS. The CDS Patent Costs paid after the first Product Profitability Date shall be paid by CDS, and Alimera shall reimburse CDS fifty percent (50%) (subject to the last sentence of this paragraph) 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 the Original 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, Alimera's share of costs for those particular 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 <u>Abandonment</u>. CDS shall not abandon prosecution or maintenance of any CDS-Prosecuted Patent Rights already pending in any country identified in <u>Exhibit 1.15</u> 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 shall 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 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 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 Party.

7.4 <u>Information Disclosure</u>; <u>Cooperation</u>. 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 nor 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 7.5 (including, where appropriate, by legal action).

7.6 Infringement

7.6.1. <u>Notification</u>. 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 any 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 7.6.1; (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 §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;
- (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 7.6.2 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 the other Party's reasonable expense, and shall offer reasonable assistance to the other Party in connection therewith at the other Party's reasonable 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 [*] in accordance with the percentages set forth in the first sentence of Section 6.5.1. 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. <u>Notification of Third Party Claim</u>. 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, 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 <u>Marking</u>. 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. §287.
- 7.8 <u>Trademarks</u>. 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 exploitation of the MEDIDUR Mark as follows: (1) CDS may, in its sole discretion and upon at least ten (10) days prior written notice, during regular business hours, carry out periodic reasonable inspections of the related operation of Alimera, its Affiliates, subcontractors and sublicensees, provided that such inspections are limited to information necessary to ensure the quality of the Products Commercialized, and (2) Alimera agrees to reasonably cooperate, and to cause its Affiliates, subcontractors and sublicensees to cooperate, with such periodic inspections of its related operations upon at least ten (10) days 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 LIMITAT

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 <u>UKRF Licenses and B&L Agreement</u>. 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; or (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. Notwithstanding any other provisions of this Article, Alimera Know-How shall be Confidential Informatio

8.2 <u>Disclosure</u>. A Party may disclose Confidential Information (a) to its employees on a need-to-know basis, provided 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; (b) to its directors, Affiliates, accountants, attorneys, lenders and other financing sources, provided that the Party making such disclosure will advise the recipients that such information is confidential and of the terms of this Section 8 and that by receiving such information, the recipients are agreeing to be bound by such provisions; (c) to Third Parties on a need-to-know basis in connection with (i) a proposed merger, acquisition or other comparable transaction solely for the purpose of evaluating, negotiating and, if

applicable, consummating such transaction, (ii) a proposed offering of securities solely for purpose of evaluating, negotiating and, if applicable, consummating such offering, (iii) strategic consulting advice solely for the purpose of rendering such advice, and (iv) a proposed license or sublicense of the technology or intellectual property, or portion thereof, licensed hereunder as permitted under this Agreement solely for the purpose of evaluating, negotiating and, if applicable, consummating such license or sublicense; provided that the Party making such disclosure in the case of (i), (ii), (iii) and (iv) will advise the recipients that such information is confidential and of the terms of this Section 8 and that such recipients shall agree in writing to non-use and non-disclosure obligations essentially the same as those set forth herein; (d) 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, Product pursuant to this Agreement; and (e) as required by any applicable law, order, regulation, rule or ruling of any governmental entity, court or stock exchange, provided that the Party required to make such disclosure will provide prompt prior written notice of such request or requirement to the other Party (if legally permissible and feasible) so that the other Party may seek, at its expense, an appropriate protective order or other remedy, and in the absence of a protective order, will consult with the other Party about the extent and nature of such disclosure, will disclose only that portion of the Confidential Information that is required or compelled to be disclosed and will exercise commercially reasonable efforts to obtain confidential

8.3 <u>Disclosure of Agreement</u>. Disclosure of the execution and terms of this Agreement shall be made in the form of a mutually acceptable press release on the Amendment Effective Date (and in the case of CDS, a report on Form 8-K); and neither Party shall make any public disclosure with respect to or describing the Agreement (including the relationship of the Parties hereunder and the terms thereof) that is contrary to or inconsistent with the substance in such press release or the Agreement.

8.4 <u>Disclosure of Product Achievements</u>. Prior to making disclosure of the achievement of any event relating to a Product, including any results of clinical trials, Alimera shall provide CDS with prompt prior written notice (if feasible) of such disclosure, will provide CDS with a copy of such disclosure reasonably in advance (together with all data underlying such disclosure unless previously provided to CDS), and will reasonably consult in advance with CDS with respect thereto.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES

- 9.1 Representations and Warranties of CDS. CDS represents and warrants as of the Amendment 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;
 - (c) CDS has taken all necessary action to authorize the execution, delivery and performance of this 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 <u>Exhibit</u> <u>1.11A</u> 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 <u>Exhibit 1.11A</u> and has not instructed its patent counsel or taken any other actions [*] any patent listed in <u>Exhibit 1.11A</u>;
- (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 Amendment 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;
- (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;
 - (f) to the knowledge of Alimera, Alimera is the sole and exclusive owner of the Alimera Know-How;
- (g) to the best of Alimera's knowledge, no claim has been threatened or asserted that the practice of any patent or patent application listed in <u>Exhibit 1.11A</u> infringes patent rights of any Third Party;
- (h) Alimera 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; and
- (i) Alimera has no present intention to seek reexamination of any patent listed in <u>Exhibit 1.11A</u> and has not instructed its patent counsel or taken any other actions to seek reexamination of any patent listed in Exhibit 1.11A.
- 9.3 <u>Warranty Disclaimer</u>. 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 <u>Limited Liability</u>. 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 7.6.4 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.
- 10.2 <u>Limitation on Indemnity Obligations</u>. 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. Notwithstanding the prior sentence, if CDS is the Indemnifying Party based on a claim for indemnification by Alimera, then Alimera agrees to use CDS' counsel as common counsel to the extent the Parties' interests are aligned; provided that if the Parties' interests diverge after they have used common counsel of CDS' choosing, the common counsel may continue to represent CDS and not be subject to disqualification on account of the common representation. 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 <u>Insurance</u>. 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 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 <u>Product Liability Claims</u>. 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 ("<u>Product Liability Losses</u>") 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 <u>Term</u>. If not earlier terminated as provided in this Article 11, the term of this Agreement (the "<u>Term</u>") 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 <u>Termination for Default by Either Party</u>. 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 11.5) 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 (60) 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. Any Event of Default pursuant to and as defined in the Alimera Note shall constitute a breach of a material term of this Agreement by Alimera. A Liquidity Event Failure pursuant to and as defined in the Alimera Note shall constitute a breach of a material term of this Agreement by Alimera. The third occurrence of an Interest Payment Default (as defined in the Alimera Note), Scheduled Payment Default (as defined in the Alimera Note), or any combination thereof, on different days and not simultaneously, (notwithstanding any intervening cure or waiver, other than a waiver in writing relating specifically to this sentence of this Section 11.2, and notwithstanding the termination of the Alimera Note) shall constitute a breach of a material term of this Agreement by Alimera. For the sake of clarity, as provided in the Alimera Note, in the event of a Liquidity Event Failure or if this Agreement shall have been terminated because there shall have occurred three Interest Payment Defaults, Scheduled Payment Defaults, or any combination thereof, on different days and not simultaneously (the simultaneous occurrence of an Interest Payment Default and a Scheduled Payment Default on the same day constituting one such occurrence), the Alimera Note shall immediately and without further action be cancelled, and Alimera shall have no obligation to pay any principal amount of such Alimera Note then outstanding or any accrued and unpaid interest thereon.

- 11.3 Intentionally omitted.
- 11.4 Intentionally omitted.
- 11.5 <u>Termination for Abandonment</u>. For purposes of this Section 11.5, "Abandonment" by Alimera or to "Abandon" shall mean delivery of a written election by Alimera to abandon this Agreement with respect to a Product. If Alimera Abandons a Product pursuant to this Section 11.5, then CDS' sole remedy shall be termination with respect to such Product pursuant to this Section 11.5 and Section 11.5.2. Solely for purposes of this Section 11.5 (including 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. Intentionally omitted.

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 under this Agreement for Abandonment of that product by Alimera, except that Alimera shall promptly pay to CDS all Development Payments that Alimera owes CDS as of the date of termination (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 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 <u>Survival of Provisions Upon Expiration or Termination</u>. 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, 11.5.2 (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 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 <u>Assignment</u>. 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: pSivida, Inc.

400 Pleasant Street Watertown, MA 02472 Attention: President Fax: (617)-926-5050

With a copy to: pSivida, 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.

Fax: (617) 951-7050

If to Alimera: Alimera Sciences, Inc.

6120 Windward Parkway, Suite 290

Alpharetta, GA 30005 Attention: President Fax: (678) 990-5744

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP With a copy to:

> 610 Lincoln Street Waltham, MA 02451

Attention: Jay Hachigian, Esq.

Fax: (781) 622-1622

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 <u>Dispute Resolution</u>. 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:
- 12.7.1. <u>Senior Management</u>. If the dispute cannot be resolved by the Primary Contact Persons in accordance with Section 3.4 hereof, 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 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

12.8 Intentionally omitted.

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 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 the Original Agreement, whereupon the provisions of such agreement shall survive to the extent set forth in that agreement.

- 12.10 <u>Headings</u>. 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 <u>Independent Contractors</u>. 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 <u>Waiver</u>. 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 <u>Counterparts</u>. 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>

IN WITNESS WHEREOF, the Parties have executed this Amended and Restated Collaboration Agreement as of the date first set forth above.

PSIVIDA, INC.

ALIMERA SCIENCES, INC.

By:/s/ Lori FreedmanBy:Name:Lori FreedmanNamTitle:VP, Corporate Affairs, General Counsel and SecretaryTitle

Name: Richard S. Eiswirth, Jr.

/s/ Richard S. Eiswirth, Jr.

Title: CFO

Amended and Restated Collaboration Agreement

ALIMERA SCIENCES, INC.

Promissory Note

\$15,000,000 March 14, 2008

FOR VALUE RECEIVED, the undersigned, ALIMERA SCIENCES, INC., a Delaware corporation (the "<u>Company</u>"), hereby promises to pay to the order of PSIVIDA INC. or registered assigns (such original payee or any assignee from time to time, the "<u>Noteholder</u>"), at the address specified in Section 6.2 hereof, or at such other place as the Noteholder shall from time to time have designated to the Company in writing, on the Liquidity Date, if and when it occurs, Fifteen Million and No/100ths Dollars (\$15,000,000.00), and to pay interest thereon as provided in Section 2 hereof.

1. THE NOTE. This Note (the "Note") is issued pursuant to and in accordance with Section 6.2A of the Amended and Restated Collaboration Agreement, dated as of March 14, 2008, between the Company, on the one hand, and pSivida, Inc., on the other hand (as amended and in effect from time to time, the "Collaboration Agreement"). The rights of the Noteholder therein shall be in addition to the rights of the Noteholder hereunder. Certain terms are used in this Note as specifically defined herein and these definitions are set forth or referred to in Section 5 hereof.

2. INTEREST PROVISIONS.

- 2.1 <u>Interest Rate</u>. This Note shall bear interest (computed on the basis of a 360-day year consisting of twelve 30-day months) from the date hereof, on the principal amount hereof from time to time unpaid, until repayment of all sums due hereunder or until such amounts are otherwise no longer payable as provided in Section 3.3 herein, at the following rates:
 - (i) From the date hereof until and including March 31, 2010, at a rate equal to 8% per annum; and
 - (ii) From and after April 1, 2010, at a rate equal to the lesser of 20% per annum and the highest rate of interest permissible under applicable law (after taking into account any notifications or filings made under applicable law).
- 2.2 <u>Interest Payment Dates</u>. Interest shall be payable in cash quarterly in arrears on the last Business Day of each of December, March, June and September, commencing on March 31, 2008; <u>provided</u>, <u>however</u>, that upon the third occurrence of an Interest Payment Default, a Scheduled Payment Default, or any combination thereof on different days and not simultaneously (the simultaneous occurrence of an Interest Payment Default and a Scheduled Payment Default on the same day constituting one such occurrence), interest shall continue to accrue hereunder, but no further quarterly payments of interest shall be required pursuant to this Section 2.2.

- 2.3 <u>Maximum Rate</u>. Notwithstanding any provisions of this Note, in no event shall the amount of interest paid or agreed to be paid by the Company exceed an amount computed at the highest rate of interest permissible under applicable law.
- 3. PAYMENT PROVISIONS. The Company covenants that so long as this Note is outstanding:
- 3.1 <u>Scheduled Payments</u>. Commencing on April 30, 2010 and on the last Business Day of each month thereafter until the Maturity Date, the Company shall make a payment of \$500,000 of the principal amount of this Note, together with all accrued and unpaid interest on the principal amount so paid; <u>provided</u>, <u>however</u>, that upon the third occurrence of an Interest Payment Default, a Scheduled Payment Default or any combination thereof on different days and not simultaneously (the simultaneous occurrence of an Interest Payment Default and a Scheduled Payment Default on the same day constituting one such occurrence), no further scheduled payments shall be required pursuant to this Section 3.1.
- 3.2 <u>Mandatory Prepayment</u>. On the Liquidity Date, the Company will pay the entire principal amount of this Note then outstanding, together with all accrued and unpaid interest thereon and any other amounts owed to the Noteholder under this Note.
- 3.3 <u>Liquidity Event Failure</u>; <u>Termination of Collaboration Agreement</u>. If no Liquidity Event shall have occurred on or before the Maturity Date (a "<u>Liquidity Event Failure</u>") or if the Collaboration Agreement shall have been terminated because there shall have occurred three Interest Payment Defaults, Scheduled Payment Defaults, or any combination thereof, on different days and not simultaneously (the simultaneous occurrence of an Interest Payment Default and a Scheduled Payment Default on the same day constituting one such occurrence), this Note shall immediately and without further action be cancelled, and the Company shall have no obligation to pay any principal amount of this Note then outstanding or any accrued and unpaid interest thereon.
- 3.4 <u>Voluntary Prepayments</u>. The Company may at any time and from time to time prepay all or part of the principal amount of this Note then outstanding without penalty or premium.
- 3.5 <u>Notice of Prepayments</u>. Notice of each voluntary prepayment of this Note pursuant to Section 3.4 hereof shall be given to the Noteholder in accordance with Section 6.2 hereof no later than one Business Day prior to the prepayment date, in each case by delivering to the Noteholder a notice of intention to prepay specifying the date of prepayment, the aggregate amount of this Note to be prepaid on such date, and the accrued interest applicable to such prepayment.
- 3.6 <u>Payment and Interest</u>. Upon each voluntary prepayment of this Note, in whole or in part, the Company will pay to the Noteholder the amount of this Note to be prepaid, as set forth in the notice delivered pursuant to Section 3.5 hereof, together with unpaid interest in respect thereof accrued to and including the prepayment date.

- 3.7 <u>Application of Payments</u>. All cash payments made by the Company hereunder shall be applied: (a) first, to the payment of any costs and expenses for which the Company is responsible under Section 3.8 hereof; (b) second, to the payment in full of accrued unpaid interest; and (c) finally, to the reduction of the unpaid principal balance hereof. Voluntary prepayments will be applied to the remaining scheduled payments under Section 3.1 hereof in inverse order of maturity.
- 3.8 <u>Noteholder Expenses</u>. The Company shall pay to the Noteholder all costs and expenses (including reasonable counsel fees) incurred by the Noteholder in connection with any proceedings or enforcement action instituted by or on behalf of the Noteholder to collect any sums due and owing by the Company under this Note.
- 3.9 Notice of Events Constituting or That May Constitute a Liquidity Event. No later than three Business Days after the occurrence thereof, the Company shall provide the Noteholder with notice in accordance with Section 6.2 hereof of the occurrence of a transaction qualifying as a Liquidity Event or the occurrence of any transaction described in the definition of "Liquidity Event."

4. DEFAULTS.

- 4.1 <u>Interest Payment Default</u>. An "<u>Interest Payment Default</u>" shall exist if the Company fails to make a payment when the same shall become due pursuant to Section 0 hereof and such failure continues for seven Business Days after the Noteholder has provided the Company with notice, in accordance with Section 6.2 hereof, of such failure. In the event of an Interest Payment Default the remedies of the Noteholder shall be as provided in the Collaboration Agreement.
- 4.2 <u>Scheduled Payment Default</u>. A "<u>Scheduled Payment Default</u>" shall exist if the Company fails to make a payment when the same shall become due pursuant to Section 2.2 hereof and such failure continues for seven Business Days after the Noteholder has provided the Company with notice, in accordance with Section 6.2 hereof, of such failure. In the event of a Scheduled Payment Default the remedies of the Noteholder shall be as provided in the Collaboration Agreement.
 - 4.3 Event of Default. An "Event of Default" shall exist if any of the following conditions or events shall occur and be continuing:
- 4.3.1 The Company shall fail to make any payment pursuant to Section 3.2 hereof when the same shall become due and (a) in the event that the Company has provided the Noteholder with notice of such Liquidity Event in accordance with Section 3.9 hereof, such failure continues for seven Business Days after the Noteholder has provided the Company with notice, in accordance with Section 6.2 hereof, of such failure and (b) in the event that the Company has not provided the Noteholder notice of such Liquidity Event in accordance with Section 3.9 hereof, and such failure continues for seven Business Days.

4.3.2 The Company shall: (i) commence a voluntary case concerning itself under Title 11 of the United States Code entitled "Bankruptcy" as now or hereafter in effect, or any successor thereto (the "Bankruptcy Code"); (ii) have commenced against it an involuntary case under said Bankruptcy Code and the petition is not dismissed within 60 days of the commencement of the case; (iii) have appointed for it a custodian (as defined in the Bankruptcy Code) to take charge of all or substantially all of its property; (iv) have filed against it any proceeding under any reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction whether now or hereafter in effect, which such proceeding remains undismissed for a period of 60 days, or shall suffer the appointment of any receiver or custodian or the like for it or a substantial part of its property which continues undischarged or unstayed for a period of 60 days; (v) make a general assignment for the benefit of its creditors; or (vi) take any corporate action for the purpose of effecting any case referred to in the foregoing clauses (i) or (v); or

4.3.3 The Company shall create or incur or permit to exist any consensual lien or other security interest of any kind upon any Collaboration Agreement Rights in favor of (a) any of the Persons set forth on Schedule A and their Affiliates or (b) any stockholder of the Company including any of such stockholder's Affiliates, other than where such lien or other security interest is created in conjunction with (i) a joint collaboration or development agreement to which the Company and such stockholder or its Affiliates is a party, and that relates to the Company's development of any Product and pursuant to which such stockholder or its Affiliates is required to make a substantial investment in the Company or any Product, or (ii) a credit or other lending agreement between the Company and such stockholder or its Affiliates, provided, that such stockholder's or such Affiliates' principal business is lending.

For the avoidance of doubt, an Interest Payment Default, a Scheduled Payment Default and a Liquidity Event Failure shall not constitute an Event of Default.

- 4.4 <u>Acceleration</u>. Upon the occurrence and during the continuance of any Event of Default, and in addition to the rights provided to the Noteholder in the Collaboration Agreement, the Noteholder may proceed to protect and enforce its rights by suit in equity, action at law and/or other appropriate proceeding, and/or may by notice to the Company declare all or any part of the unpaid principal amount of this Note then outstanding to be forthwith due and payable (each, an "<u>Acceleration</u>") and thereupon such unpaid principal amount or part thereof, together with interest accrued thereon and all other sums, if any, payable under this Note, shall become so due and payable without presentation, presentment, protest or further demand or notice of any kind, all of which are hereby expressly waived, and such holder or holders may proceed to enforce payment of such amount or part thereof in such manner as it or they may elect.
- 4.5 <u>Annulment of Defaults</u>. None of an Event of Default, an Interest Payment Default or a Scheduled Payment Default shall be deemed to be in existence for any purpose of this Agreement if the Noteholder shall have waived such event in writing or stated in writing that the same has been cured to the Noteholder's reasonable satisfaction. No waiver or statement of satisfactory cure pursuant to this Section 4.5 shall extend to or affect any subsequent or other Event of Default, Interest Payment Default or Scheduled Payment Default not specifically identified in such waiver or statement of satisfactory cure or impair any of the rights of any holder of this Note upon the occurrence thereof.

5. DEFINED TERMS.

5.1 <u>Cross Reference Table</u>. The following terms defined elsewhere in this Note in the Sections set forth below shall have the respective meanings therein defined

<u>Term</u>	Definition
"Acceleration"	Section 4.4
"Bankruptcy Code"	Section 4.3.2
"Collaboration Agreement"	Section 1
"Company"	Preamble
"Event of Default"	Section 4.3
"Interest Payment Default"	Section 4.1
"Liquidity Event Failure"	Section 3.3
"Note"	Section 1
"Noteholder"	Preamble
"Scheduled Payment Default"	Section 4.2

5.2 Other Defined Terms. As used in this Note, the following terms will have the following meanings:

"Business Day" shall mean each day of the week excluding Saturday, Sunday, U.S. federal holidays and U.S. bank holidays.

"Collaboration Agreement Rights" means any of the Company's rights under the Collaboration Agreement, including rights to any Product (as defined in the Collaboration Agreement) or to any CDS Technology (as defined in the Collaboration Agreement), as well as any revenues or royalties related to any Product (as defined in the Collaboration Agreement) or to any CDS Technology (as defined in the Collaboration Agreement), whether now owned or hereafter acquired.

"<u>Liquidity Date</u>" means the date three Business Days following the date on which a Liquidity Event shall have occurred, provided such date shall be on or before the Maturity Date.

"<u>Liquidity Event</u>" means the consummation of (i) any of the following events for which the proceeds are not less than \$75,000,000 or (ii) any of the following events, related or unrelated, which when combined with any one or more of the following events that have been consummated have proceeds from all such events that aggregate not less than \$75,000,000:

(a) a public offering of the common stock of the Company, any of its Subsidiaries or any of their respective successors, registered under the Securities Act of 1933, as amended, by any of the Company, any of its Subsidiaries or any of their respective successors and/or any of their respective security holders (for which event proceeds shall mean the aggregate gross proceeds to the Company, any of its Subsidiaries, and/or any of their respective successors and/or security holders);

(b) (i) any event or series of events, whether related or unrelated, prior to the Company's initial public offering, as a result of which the Persons set forth on Schedule A hereto, who are the beneficial owners of the securities of the Company on the date hereof no longer (x) have the direct or indirect power to elect a majority of the board of directors of the Company or any of its successors, or (y) are beneficial owner(s) of at least fifty percent (50%) of the outstanding securities of the Company or any surviving entity or any of its successors and (ii) after the Company's initial public offering, any event or series of related events as a result of which the beneficial owners of the securities of the Company immediately prior thereto (x) no longer have the direct or indirect power to elect a majority of the board of directors of the Company or any of its successors, or (y) no longer are beneficial owner(s) of at least fifty percent (50%) of the outstanding securities of the Company or any surviving entity or any of its successors, or (z) transfer securities of the Company representing 50% or more of the combined voting power of the then outstanding securities of the Company (other than in connection with the Company's initial public offering or a distribution by a limited partnership to the limited partners in accordance with the terms of the partnership agreement) (for each of such event, proceeds shall mean the aggregate net proceeds to the Company and/or any of its successors and/or its security holders);

(c) any event or transaction involving the Company, any of its Subsidiaries, and/or any of their respective successors (other than the issuance by the Company of shares of its Series C Preferred Stock pursuant to that certain Series C Preferred Stock Purchase Agreement, dated on or about the date hereof), involving the sale, issuance, conversion, exchange, exercise, transfer or other event with respect to the capital stock of the Company, any of its Subsidiaries, and/or any of their respective successors, or securities exercisable for, convertible into or otherwise representing the right to acquire such capital stock (including, without limitation, resulting from a merger, consolidation, exchange, tender offer, corporate combination, reorganization, restructuring, recapitalization, stock or other security issuance, securities conversion, exercise or similar transaction, but excluding, however, issuances of options to employees of the Company in the ordinary course of business) (for which event or transaction proceeds shall mean the gross proceeds to the Company, any of its Subsidiaries, and/or any of their respective successors other than events included pursuant to (1)(a) above, for which proceeds shall be as defined therein); or

(d) any sublicense of rights under the Collaboration Agreement (for which sublicense proceeds shall mean the share of royalty and/or non-royalty consideration received by the Company, any of its Subsidiaries, and/or any of their respective successors or security holders, as applicable, after deduction of amounts paid by the Company to pSivida, Inc. and/or its successors and assigns and other amounts paid by the Company and permitted to be deducted pursuant to Section 6.6 of the Collaboration Agreement, in each case with respect to such sublicense); or

(e) any sale, transfer or other disposition of all or substantially all of the assets of the Company (for each of such event, proceeds shall mean the aggregate net proceeds to the Company, its Subsidiaries and/or any of their respective successors and/or its security holders).

For purposes of this definition, any noncash proceeds shall be valued at fair market value as determined by mutual agreement of the Company and the Noteholder acting in good faith. In the event that the Company and the Noteholder fail to reach such mutual agreement, the matter shall be resolved by arbitration in accordance with Section 12.7.2 of the Collaboration Agreement.

"Maturity Date" means September 30, 2012.

"Person" means any individual or corporation, partnership, association, limited liability company, joint venture, trust, governmental authority or other entity of any kind.

"Product" shall have the meaning given such term in the Collaboration Agreement.

"Subsidiary" means any Person of which the Company (or other specified Person) shall at the time, directly or indirectly through one or more of its Subsidiaries, (a) own more than 50% of the outstanding capital stock (or other shares of beneficial interest) entitled to vote generally, (b) hold more than 50% of the partnership, joint venture or similar interests or (c) be a general partner or joint venturer.

6. MISCELLANEOUS.

- 6.1 <u>Assignment</u>. This Note shall be binding upon the Company and its successors and assigns and shall inure to the benefit of the Noteholder and its successors and assigns. Neither the Company's rights or obligations hereunder nor any interest therein may be assigned or delegated by the Company without the prior written consent of the Noteholder. The Noteholder shall have the right at any time to sell, assign or transfer, in whole or in part, this Note.
- 6.2 <u>Notices</u>. Any notice or other communication to the Company or the Noteholder in connection with this Note must be in writing and must be delivered: (a) by hand (in which case it will be effective upon delivery), (b) by facsimile (in which case it will be effective upon receipt of confirmation of good transmission), or (c) by overnight delivery by a nationally recognized courier service (in which case it will be effective on the Business Day after being deposited with such courier service), and in each case, to the address (or facsimile number) listed below:

If to the Company, to it at:

Alimera Sciences, Inc. 6120 Windward Parkway, Suite 290 Alpharetta, GA 30005 Attn: Chief Executive Officer Telephone: 678-990-5740 Fax: 678-990-5744

With a copy to:

Gunderson Dettmer Stough Villeneuve Franklin & Hachigian, LLP 610 Lincoln Street Waltham, MA 02451 Attn: Jay Hachigian, Esq. Telephone: 781-795-3550

If to the Noteholder, to it at:

pSivida, Inc. 400 Pleasant Street Watertown, MA 02472 Attn: Chief Financial Officer Telephone: 617-926-5000 Fax: 617-926-5050

Fax: 781-622-1622

With a copy to:

Ropes & Gray LLP One International Place Boston, MA 02110 Attn: Mary Weber, Esq. Telephone: 617-951-7000 Fax: 617-951-7050

6.3 <u>Waiver of Jury Trial</u>. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW WHICH CANNOT BE WAIVED, THE COMPANY (BY ITS EXECUTION HEREOF) AND THE NOTEHOLDER (BY ITS ACCEPTANCE OF THIS NOTE) WAIVES AND COVENANTS THAT IT WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE) ANY RIGHT TO TRIAL BY JURY IN ANY FORUM IN RESPECT OF ANY ISSUE OR ACTION ARISING OUT OF OR BASED UPON OR RELATING TO THIS NOTE OR IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE TRANSACTIONS CONTEMPLATED HEREBY, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING.

6.4 <u>Governing Law</u>. This Note shall be deemed to be a contract made under the laws of the Commonwealth of Massachusetts and for all purposes shall be governed by, construed under, and enforced in accordance with the laws (other than the conflict of laws rules) of the Commonwealth of Massachusetts.

EXHIBIT 6.2A NOTE

Promissory Note \$15,000,000

The undersigned has caused this Note to be executed under seal by a duly authorized officer as of the date first written above.

ALIMERA SCIENCES, INC.

By		
Name:		
Title:		

Deed of Release

pSivida Limited

ACN 009 232 026

Aaron Finlay

Blake Dawson

Level 32, Exchange Plaza 2 The Esplanade Perth WA 6000 Australia T 61 8 9366 8000 F 61 8 9366 8111

Reference

09-1412-4432

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	Blake Dawson
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DEED OF RELEASE

DEED made 29 February 2008

PARTIES

pSivida Limited ACN 009 232 026 of Level 12, BGC Centre, 28 The Esplanade, Perth, Western Australia 6000 (**pSivida**) **Aaron Finlay** of 34 Webster Street, Nedlands, WA 6009 (**Finlay**)

RECITALS

- A. Finlay was employed in the position of company secretary of pSivida from 3 May 2004, based in Perth, Western Australia (the Employment).
- B. Finlay is the company secretary and an officer of pSivida, and pSiNutria Limited and a member of the board of pSiNutria Limited.
- C. The Employment will terminate on 28 February 2008 (the **Termination**) on the ground of redundancy as a result of pSivida:
 - (a) undertaking a reconstruction scheme of arrangement under section 413 of the Corporations Act (cth) 2001 (the Reconstruction); and
 - (b) ceasing to be an Australian listed company.
- D. Finlay will resign from the Offices on or before the Termination (the **Resignation**).
- E. Finlay will be involved in the provision of consultancy services to pSivida for a period of 6 months following the Termination.

OPERATIVE PROVISIONS

1. INTERPRETATION

1.1 Definitions

The following definition applies in this document.

Group means:

- (a) pSivida;
- (b) any entity that is connected with pSivida or any other member of the Group by a common interest in an economic enterprise, for example, a partner or another member of a joint venture;
- (c) any entity that controls, is controlled by or is under common control with pSivida; and
- (d) any related body corporate (as that term is defined by the *Corporations Act 2001* (Cth)) or a joint venture partner, including but not limited to:
 - (i) pSivida Inc;
 - (ii) pSiMedica Limited;
 - (iii) pSiOncology Limited; and

(iv) pSiNutria Limited,

and each of their respective officers, employees and agents.

Offices means all offices (which includes all directorships and positions) held by Finlay with any member of the Group, including but not limited to:

- (a) company secretary and officer of pSivida; and
- (b) company secretary and member of the board of pSiNutria Limited.

1.2 Rules for interpreting this document

Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this document, except where the context makes it clear that a rule is not intended to apply.

- (a) A reference to:
 - a document or agreement, or a provision of a document or agreement, is to that document, agreement or provision as amended, supplemented, replaced or novated;
 - (ii) a party to this document or to any other document or agreement includes a permitted substitute or a permitted assign of that party;
 - (iii) a person includes any type of entity or body of persons, whether or not it is incorporated or has a separate legal identity, and any executor, administrator or successor in law of the person; and
 - (iv) anything (including a right, obligation or concept) includes each part of it.
- (b) A singular word includes the plural, and vice versa.
- (c) A word which suggests one gender includes the other genders.
- (d) If a word is defined, another part of speech has a corresponding meaning.
- (e) If an example is given of anything (including a right, obligation or concept), such as by saying it includes something else, the example does not limit the scope of that thing.
- (f) A reference to **Group** includes any member of the Group.
- (g) A reference to **dollars** or \$ is to an amount in Australian currency.

1.3 Multiple parties

If a party to this document is made up of more than one person, or a term is used in this document to refer to more than one party:

- (a) an obligation of those persons is joint and several;
- (b) a right of those persons is held by each of them severally; and
- (c) any other reference to that party or term is a reference to each of those persons separately, so that (for example) a representation, warranty or undertaking is given by each of them separately.

2. TERMINATION OF EMPLOYMENT AND RESIGNATION FROM OFFICES

- 2.1 Finlay and pSivida agree to terminate the Employment, with effect 28 February 2008.
- 2.2 Finlay through Sol Capital Pty Ltd (ACN 129 790 478) will provide services to pSivida in accordance with a new consultancy agreement commencing 29 February 2008, the essential terms of which will include:
 - (a) a six month term;
 - (b) a monthly contract fee, the total cost of which to pSivida over the term will not exceed A\$78,000 (exclusive of GST); and
 - (c) pSivida will provide Finlay with use of a laptop computer, blackberry, mobile telephone and desktop computer for the term of the consultancy agreement.
- **2.3** Prior to, or immediately upon execution of this document, Finlay will resign from each of the Offices and will execute all documents and do all things necessary to effect these resignations.
- 2.4 If Finlay does not immediately resign from each of the Offices Finlay authorises pSivida (or any persons authorised by pSivida) to do all things and execute all documents necessary on behalf of Finlay to effect his resignation from each of the Offices.

3. PROVISION OF BENEFITS TO FINLAY

- **3.1** pSivida has already paid or will pay (as applicable) to Finlay:
 - (a) the amount of \$22,916.66 (gross) in respect of the balance of all outstanding salary payable up to 28 February 2008 in relation to the Employment (already paid);
 - (b) the amount of \$140,000 (gross) by reason of the bona fide redundancy of Finlay (to be paid at the end of March 2008); and
 - (c) the amount of \$14,102.56 (gross) in respect of all accrued annual leave payable up to 28 February 2008 in relation to the Employment (to be paid at the end of March 2008),

(together the Payment).

- **3.2** pSivida will withhold from the Payment all amounts pSivida considers necessary for pSivida to comply with pSivida's taxation obligations under Australian taxation legislation.
- **3.3** Finlay will provide pSivida a copy of this document properly executed by Finlay in exchange for the Payment.
- 3.4 Finlay agrees that the Payment and the consultancy agreement referred to in clause 2.2 of this document:
 - (a) includes the full amount, and compensation in lieu of any amount, that pSivida or the Group owes Finlay under the Employment or any contract or arrangement, including any contract of employment or otherwise, whether for fees, salary, wages, bonus payments, options or other remuneration, leave entitlements, payment in lieu of notice, severance pay, or anything else connected with the Employment, the Termination, the Offices and the Resignation;

(b) but does not include any payment with respect to the options referred to under clause 4.

4. OPTIONS

To the extent permissible by law:

- (a) all options in pSivida held by or on behalf of Finlay at the date of the Termination will continue to be held by or on behalf of Finlay until 31 December 2010 in accordance with any relevant rules or plan that applied in relation to the issue of such options, as amended for any necessary changes required in respect of the implementation of the Reconstruction;
- (b) all unvested options in pSivida held by Finlay on 1 January 2011 will be automatically cancelled by the Group; and
- (c) each option in pSivida held by or on behalf of Finlay that has vested before 31 December 2010 will remain exercisable for the duration of the option subject to its terms of grant and in accordance with the terms of any relevant rules or plan that apply in relation to the issue (as amended for any necessary changes required in respect of the implementation of the Reconstruction) and/or exercise of such options notwithstanding Finlay is no longer company secretary or an officer of pSivida or contractor to pSivida.

5. RELEASES RELATING TO THE OFFICES

- 5.1 Finlay releases each member of the Group from all claims and liability arising, directly or indirectly, out of the Offices and the Resignation. This release covers all claims and liability, however described and however arising, including all claims and liability under legislation. It covers claims by, and liability to, anyone who claims through Finlay. It covers claims and liability that arise in the future. It covers all claims whether or not such claims are presently within the contemplation of any party and whether or not the facts or law giving rise to any such claim are presently within the belief or knowledge of any party.
- 5.2 The Group releases Finlay from all claims and liability in connection with matters which are within the knowledge of its senior management or Board arising directly or indirectly out of the Offices and the Resignation. The release in this clause does not extend to:
 - (a) any conduct which constitutes negligence or misconduct on the part of Finlay;
 - (b) any breach of confidentiality by Finlay;
 - (c) any criminal offence committed by Finlay; or
 - (d) any claim, action or demand which the Group has, and which is revealed or comes to its knowledge after the date of this document.

6. RELEASES RELATING TO EMPLOYMENT AND TERMINATION

- **6.1** This document and the consultancy agreement referred to in clause 2.2 of this document fully satisfy the rights that Finlay, and anyone who claims through Finlay has or may have against the Group arising directly or indirectly out of the Employment and the Termination.
- **6.2** Finlay releases each member of the Group from all claims and liability arising directly or indirectly out of the Employment and the Termination save for claims for the contract fee for services provided under the consultancy agreement referred to in clause 2.2 of this document.

6.3 This release covers all claims and liability, however described and however arising, including all claims and liability under legislation. It covers claims by, and liability to, anyone who claims through Finlay. It covers claims and liability that arise in the future. It covers all claims whether or not such claims are presently within the contemplation of any party and whether or not the facts or law giving rise to any such claim are presently within the belief or knowledge of any party.

6.4 This release:

- (a) includes (but is not limited to) all claims and liability under the *Workplace Relations Act* 1996 (Cth), *Industrial Relations Act* 1979 (WA), *Minimum Conditions of Employment Act* 1993 (WA), *Trade Practices Act* 1974 (Cth), *Fair Trading Act* 1987 (WA), anti-discrimination legislation, or for breach of contract or any common law or equitable claim; but
- (b) does not apply to any claim or liability in respect of workers' compensation under applicable legislation.
- 6.5 Notwithstanding the provisions of this clause 6, nothing in this clause 6 shall operate to negate any existing obligations of any member of the Group to indemnify and to keep indemnified Finlay in relation to any claim made against Finlay arising out of the lawful and reasonable discharge by Finlay of his duties in connection with the Offices and the Employment.

7. RETURNING PROPERTY

- **7.1** Prior to, or immediately upon execution of this document, and except as the continued possession of such property is directly relevant to the performance of work by Finlay for pSivida under the consultancy agreement referred to in clause 2.2 of this document, Finlay must return to pSivida:
 - (a) all property belonging to the Group or its customers or clients (for example, cards, keys, equipment and materials) that Finlay has, or should have and can reasonably obtain; and
 - (b) all material that Finlay has, or should have and can reasonably obtain, that contains confidential information relating to the Group's business, organisation or affairs.
- 7.2 In this clause, material includes anything on which information is recorded, for example, documents, computer disks and computer records.

8. CONFIDENTIAL INFORMATION AND CONTINUING OBLIGATIONS

Finlay remains under an ongoing duty not to use or disclose any confidential information belonging to the Group.

9. BAR TO PROCEEDINGS

9.1 Each member of the Group may use this document, including as a bar, against Finlay in any court or other proceedings brought by Finlay (or anyone who claims through Finlay).

9.2 Finlay may use this document, including, to the extent provided by this document, as a bar, against each member of the Group in any court or other proceedings brought by any member of the Group.

10. ACKNOWLEDGEMENTS BY FINLAY

Finlay acknowledges and agrees that:

- (a) Finlay has had a reasonable opportunity to obtain legal advice about this document; and
- (b) the terms of this document are fair and reasonable.

11. KEEPING THIS DOCUMENT CONFIDENTIAL

- 11.1 The wording of an appropriate announcement regarding the Termination and the Resignation has been agreed between pSivida and Finlay.
- **11.2** Other than in accordance with the announcement referred to in clause 11.1, Finlay must not disclose the content of this document or any discussions and correspondence relating to the negotiation of this document, unless pSivida first agrees in writing.
- **11.3** Clause 11.2 does not prevent Finlay disclosing information to Finlay' lawyer or accountant, respectively, on a confidential basis or where the law says information must be disclosed (for example, in a tax return).

12. BENEFIT OF THIS DOCUMENT

pSivida has the benefit of this document for itself and also in trust for each member of the Group, any of whom may independently enforce it against Finlay.

13. AMENDMENT

This document can only be amended, supplemented, replaced or novated by another document signed by the parties.

14. GENERAL

14.1 Governing law

- (a) This document is governed by the law in force in Western Australia.
- (b) Each party submits to the non-exclusive jurisdiction of the courts exercising jurisdiction in Western Australia, and any court that may hear appeals from any of those courts, for any proceedings in connection with this document, and waives any right it might have to claim that those courts are an inconvenient forum.

14.2 Costs

Each party agrees to pay its own costs of and incidental to this document.

14.3 Giving effect to this document

Each party must do anything (including execute any document), and must ensure that its employees and agents do anything (including execute any document), that any other party may reasonably require to give full effect to this document.

14.4 Waiver of rights

A right may only be waived in writing, signed by the party giving the waiver, and:

- (a) no other conduct of a party (including a failure to exercise, or delay in exercising the right) operates as a waiver of the right or otherwise prevents the exercise of the right; and
- (b) a waiver of a right on one or more occasions does not operate as a waiver of that right if it arises again; and
- (c) the exercise of a right does not prevent any further exercise of that right or of any other right.

14.5 Operation of this document

- (a) This document and the consultancy agreement referred to in clause 2.2 of this document contain the entire agreement between the parties about its subject matter. Any previous understanding, agreement, representation or warranty relating to that subject matter is replaced by this document and has no further effect.
- (b) Any provision of this document which is unenforceable or partly unenforceable is, where possible, to be severed to the extent necessary to make this document enforceable, unless this would materially change the intended effect of this document.

14.6 Counterparts

This document may be executed in counterparts.

	Blake Dawson
EXECUTED as a Deed.	
EXECUTED by pSivida Limited ACN 009 232 026:	
	/s/ Lori Freedman
	Signature of director/secretary
	Lori Freedman, VP, Corporate Affairs, General Counsel and Company Secretary Name
EXECUTED by Aaron Finlay in the presence of:	/s/ Aaron Finlay
•	Aaron Finlay
/s/ Elizabeth Svendsen	
Signature of witness	
Elizabeth Svendsen	
Name	

Contractor Agreement

pSivida Limited

ACN 009 232 026

Sol Capital Pty Ltd

ACN 129 790 478

Blake Dawson

Level 32, Exchange Plaza 2 The Esplanade Perth WA 6000 Australia T 61 8 9366 8000 F 61 8 9366 8111

Reference

09-1412-4432

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Contractor Agreement

DATE 29 February 2008

PARTIES

pSivida Limited ACN 009 232 026 of Level 12, BGC Centre, 28 The Esplanade, Perth WA 6000 (the **Principal**) Sol Capital Pty Ltd ACN 129 790 478 of Level 12, BGC Centre, 28 The Esplanade, Perth WA 6000 (the **Contractor**)

RECITALS

D.

- A. Mr Aaron Finlay (Finlay) was employed by the Principal from 3 May 2004 as company secretary of the Principal (the Employment).
- B. Finlay was also the company secretary of pSiNutria Limited and a member of the board of pSiNutria Limited.
- C. The Employment was terminated on the ground of redundancy on 28 February 2008 (the **Termination**) as a result of the Principal:
 - (a) undertaking a reconstruction scheme of arrangement under section 413 of the Corporations Act (Cth) 2001; and
 - (b) ceasing to be an Australian listed company.
 - Finlay resigned from the Offices on or before the Termination (the **Resignation**).
- E. Finlay and the Principal, executed a Deed of Release with respect to the Employment, the Offices, the Termination and the Resignation (the **Deed**).
- F. Finlay has intimate knowledge of the business, trade secrets, functions and work performed by employees of the Principal, customers and clients and processes and operations (among other things) of the Principal. As a condition precedent to completion of the Deed, the Principal and the Contractor have agreed that the Principal will engage the Contractor as a contractor to provide Finlay's personal services to the Principal in accordance with this Agreement.
- G. The Contractor has agreed to accept the appointment as a contractor to the Principal and to provide the Services to the Principal as and when required by the Principal in accordance with this Agreement.

OPERATIVE PROVISIONS

1. INTERPRETATION

1.1 Definitions

The following definitions apply in this Agreement.

Additional Invoice is defined in clause 5 of this Agreement.

Agreement means this agreement as amended from time to time in writing and signed by the Parties.

Commencement Date means 29 February 2008.

Confidential Information means (a) during the term, all information marked as confidential or advised in writing as being confidential in any form or medium concerning any past, present or future business, operations or affairs of the Principal, or of any customer of the Principal and (b) after the term all information described in (a) above whether or not so marked. Confidential Information includes but is not limited to:

- (a) all technical or non-technical data, formulae, patterns, programs, devices, methods, techniques, plans, drawings, models and processes, source and object code, software and computer records;
- (b) all business and marketing plans and projections, details of agreements and arrangements with third parties, and customer and supplier information and lists;
- (c) all financial information, pricing schedules and structures, product margins, remuneration details and investment outlays;
- (d) all information concerning any employee, customer, Contractor or agent of the Principal;
- (e) the Principal's policies and procedures; and
- (f) all information contained in this Agreement,

but Confidential Information excludes information that has come into the public domain other than by a breach of this Agreement.

Contractor means Sol Capital Pty Ltd ACN 129 790 478.

Finlay means Aaron Finlay.

GST means the same as in the GST Law.

GST Law means the same as "GST law" means in A New Tax System (Goods and Services Tax) Act 1999 (Cth).

Intellectual Property Rights means all present and future rights conferred by statute, common law or equity in or in relation to copyright, trade marks, designs, patents, circuit layouts, plant varieties, business and domain names, inventions and confidential information, and other results of intellectual activity in the industrial, commercial, scientific, literary or artistic fields whether or not registrable, registered or patentable.

These rights include:

- a) all rights in all applications to register these rights;
- b) all renewals and extensions of these rights; and
- c) all rights in the nature of these rights, such as Moral Rights.

Invoice is defined in clause 5 of this Agreement.

Materials means works, ideas, concepts, designs, inventions, developments, improvements, systems or other material or information, created, made or discovered by the Contractor (either alone or with others and whether before or after the Commencement Date) in the course of the Contractor's engagement or as a result of using the resources of the Principal, or in any way relating to any business of the Principal.

Moral Rights means rights of integrity of authorship, rights of attribution of authorship, rights not to have authorship falsely attributed and rights of a similar nature, that exist, or may come to exist, anywhere in the world in all Materials made or to be made by the Contractor in the course of the Contractor's engagement.

Monthly Fee is defined in clause 4 of this Agreement.

Offices means all offices held by Finlay with the Principal and related bodies corporate, including but not limited to:

- (a) company secretary and officer of the Principal; and
- (b) company secretary and member of the board of pSiNutria Limited.

Party means a party to this Agreement.

Principal means pSivida Limited ACN 009 232 026.

Services means the services the Principal and the Contractor agree from time to time as relevant to the Principal's operations and that are within the scope of the Contractor's competence.

Term means the period of 6 months from the Commencement Date.

1.2 Rules for interpreting this Agreement

Headings are for convenience only, and do not affect interpretation. The following rules apply in interpreting this Agreement, except where the context makes it clear that a rule is not intended to apply.

- (a) A reference to:
 - (i) any legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced, and includes any subordinate legislation issued under it;
 - (ii) a policy, document or agreement, or a provision of a policy, document or agreement, is to that policy, document, agreement or provision as amended, supplemented, replaced or novated;
 - (iii) a Party to this Agreement or to any other document or agreement includes a permitted substitute or a permitted assign of that Party;
 - (iv) a person includes any type of entity or body of persons, whether or not it is incorporated or has a separate legal identity, and any executor, administrator or successor in law of the person; and
 - (v) anything (including a right, obligation, or concept) includes each part of it.
- (b) A singular word includes the plural, and vice versa.
- (c) A word which suggests one gender includes the other gender.
- (d) If a word is defined, another part of speech has a corresponding meaning.

- (e) If an example is given of anything (including a right, obligation or concept), such as by saying it includes something else, the example does not limit the scope of that thing.
- (f) A reference to **dollars** or \$ is to an amount in Australian currency.

2. TERM OF AGREEMENT

- 2.1 This Agreement commences on the Commencement Date and will continue until:
 - (a) expiration of the Term, unless this Agreement is extended in accordance with clause 2.2 of this Agreement; or
 - (b) it is terminated earlier in accordance with clause 11 of this Agreement.
- 2.2 If the Principal and the Contractor agree, in writing, then this Agreement will continue to apply after the expiration of the Term on a month-to-month basis. Either party may terminate the Agreement at any time after the expiration of the Term by providing the other party with one month's written notice or payment in lieu of notice.

3. PROVISION OF SERVICES

3.1 Services

- (a) The Contractor will ensure the Services are provided in a proper and efficient manner in accordance with the terms of this Agreement.
- (b) The Contractor will ensure that the Services are performed diligently, competently, with care and skill in a proper and professional manner.

3.2 Provision of the Services

The Contractor will provide the Services at such reasonable times as the Principal and Contractor agree to a maximum of two days per week.

3.3 Location and facilities

- (a) The Contractor will provide the Services from a home office located at Finlay's home, or at any other premises as the Contractor may determine in its sole discretion;
- (b) The Principal will provide the Contractor use of a laptop computer, blackberry, mobile phone and desktop computer for the Term.

3.4 Warranty

The Principal does not warrant that the Contractor has preference or priority in providing any service to the Principal.

3.5 Services to be provided by Finlay on behalf of the Contractor

(a) Finlay is required to provide the Services to the Principal on behalf of the Contractor. The Services are not to (and cannot) be provided through any other person (e.g. an employee, contractor or agent of the Contractor).

- (b) Finlay is made available by the Contractor to provide Services to the Principal pursuant to this Agreement. Finlay is solely the employee or subcontractor of the Contractor and will not be construed to be the employee or sub-contractor of the Principal. Nor will the relationship between the Principal and Finlay be construed as one of employer and employee.
- (c) The Contractor will contract with Finlay to ensure that Finlay has obligations to the Contractor similar to the Contractor's obligation in clauses 6, 8 and 9 of this Agreement.

4. MONTHLY FEE

4.1 Monthly Fee

As full consideration for the provision of the Services, the Principal will pay the Contractor a fee of \$13,000 gross per month (the **Monthly Fee**). The Monthly Fee is exclusive of GST.

4.2 Additional hours

If requested in writing by the Principal to work additional hours per month, the Principal will pay the Contractor an hourly rate of \$240 per hour (exclusive of GST).

4.3 Reimbursement of expenses

The Contractor is not entitled to reimbursement by the Principal for any expenses incurred in providing the Services except with the Principal's prior written approval.

4.4 Full payment for the Services

The Contractor agrees that payment of the amounts provided for in this clause constitute full payment for the provision of the Services, and the Principal is not liable to pay any other amount to the Contractor.

5. INVOICES

5.1 Invoice Period

The Contractor will issue an invoice for the Monthly Fee each month in arrears (the **Invoice**) and also an additional invoice each month detailing any requested additional hours worked and any pre-approved amounts claimed for reimbursement in than month (the **Additional Invoice**).

5.2 Payment of invoice

The Principal will pay each Invoice and Additional Invoice within 7 days of receipt by the Principal of the Invoice and Additional Invoice and any supporting documentation reasonably required by the Principal.

5.3 Withholding reimbursement

The Principal may withhold any payment (or part of any payment) due to the Contractor under any Additional Invoice until the Contractor provides any supporting documentation reasonably required by the Principal (e.g. documentation supporting the reimbursement for expenses incurred).

6. CONFIDENTIAL INFORMATION

6.1 Confidential Information

The Contractor acknowledges that all Confidential Information of the Principal which has or may come into the possession of the Contractor remains the property of the Principal.

6.2 Non-disclosure

The Contractor must not, unless the Principal has first agreed in writing:

- (a) disclose to anyone else, or
- (b) use for a purpose other than the provision of the Services,

any of the Confidential Information either before or after the expiration or termination of the Term and/or this Agreement.

6.3 Return of Confidential Information

On termination or expiry of this Agreement, the Contractor must immediately return or cause to be returned, all originals and copies of any Confidential Information in its possession.

7. PRIVACY

- 7.1 The Contractor must comply with his obligations under the *Privacy Act 1988* (Cth).
- 7.2 The Contractor consents to the Principal collecting, using and disclosing information about the Contractor and the Services provided by the Contractor to the extent the Principal is carrying out its legitimate business. For example, that collection, use or disclosure may involve the Principal collecting information from or disclosing information to its accountants, lawyers, staff, customers or suppliers, insurers and other third parties for business reasons.

8. INTELLECTUAL PROPERTY

- 8.1 In this clause Intellectual Property means all present and future rights whether or not conferred by statute, common law or equity in or in relation to any copyright, trade marks (including service marks), designs, business and domain names, circuit layouts, trade secrets, inventions (including patents), Confidential Information and know how and other results in the industrial, commercial, scientific, literary or artistic fields (whether registered or not and whether protected by statute or not).
- **8.2** The Contractor as beneficial owner assigns to the Principal absolutely all Intellectual Property in any material, work, ideas, concepts, designs, developments, improvements, systems, software, agreements or other materials prepared or created by the Contractor in connection with this Agreement or the provision of the Services (the **Materials**).
- **8.3** The Contractor must do all things necessary or desirable to give full effect to the assignment under this clause to the Principal.

8.4 The Contractor warrants that:

- (a) the Materials, or the use or reproduction of the Materials, will not infringe the Intellectual Property Rights of any person; and
- (b) except as required by this clause, the Contractor will not assign, license or otherwise deal with the Materials.
- **8.5** On termination or expiry of this Agreement the Contractor must immediately deliver to the Principal all originals and copies of Materials in its possession or Materials that it can otherwise reasonably obtain.
- **8.6** Nothing in this Agreement prevents the Contractor from using any materials, software, formats and precedents that the Contractor owned or was licensed to use at the Commencement Date, whether or not the Principal has acquired rights under this Agreement (or otherwise) to any adaptation or reproduction of them through the Contractor's provision of the Services.

9. OCCUPATIONAL HEALTH AND SAFETY

The Contractor must comply with occupational health and safety legislation and all occupational health and safety policies and procedures issued by the Principal from time to time.

10. TAXATION

10.1 Definitions in this clause

Words defined in the GST Law have the same meaning in this clause, unless it is clear that a different meaning is intended.

10.2 Payment of GST

In addition to paying the Monthly Fee under clause 4 or other consideration (which is exclusive of GST) the Principal must:

- (a) pay to the Contractor an amount equal to any GST payable for anything provided or supplied by the Contractor in connection with this Agreement; and
- (b) make that payment as and when the Principal must pay or provide the Monthly Fee or other consideration, but the Principal need not pay until 7 days after receiving a tax invoice.

10.3 Tax invoice

The Contractor must issue a tax invoice (or an adjustment note) to the Principal for any supply for which the Contractor may recover GST from the Principal under this Agreement.

10.4 Overpayment

The Contractor must refund to the Principal any overpayment by the Principal for GST within 14 days of the Contractor becoming aware of the overpayment.

10.5 Claim for a cost

If a Party has a claim for a cost on which the Party must pay GST, the claim is for the cost plus all GST (except any GST for which that Party is entitled to an input tax credit).

10.6 Contractor must be registered for GST

The Contractor must be registered for GST purposes. If the Contractor is not registered for GST the Principal will have no obligation under this clause to pay GST to the Contractor.

TERMINATION

11.1 Expiry of Term

Unless terminated earlier in accordance with clause 11.2 of this Agreement or extended in accordance with clause 2.2 of this Agreement this Agreement will terminate by the effluxion of time (without either Party having to provide notice or payment in lieu of notice) on expiry of the Term.

11.2 Early termination

- (a) At any time prior to the expiry of the Term either Party may terminate this Agreement by providing the other Party with one month's written notice or payment in lieu of notice.
- If the Principal terminates this Agreement in accordance with clause 11.2(a), the Principal will pay to the Contractor an amount equivalent to the (b) Monthly Fee for each month remaining in the Term after the expiry of the notice period.

11.3 No additional payment

The Contractor acknowledges that termination of this Agreement does not entitle it to any form of payment or compensation by the Principal, except for payment of the Monthly Fee for the relevant notice period and, in the case of termination by the Principal, for each month remaining in the Term.

AMENDMENT

This document can only be amended, supplemented or replaced by another document signed by the parties.

13. GENERAL

13.1 Governing law

This Agreement is governed by the law in force in Western Australia.

13.2 Operation of this document

This Agreement contains the entire agreement between the parties about its subject matter. Any previous understanding, agreement, representation or warranty relating to that subject matter is replaced by this document and has no further effect.

(b) Any provision of this Agreement which is unenforceable or partly unenforceable is, where possible, to be severed to the extent necessary to make this Agreement enforceable, unless this would materially change the intended effect of this Agreement.

13.3 Inconsistency with other documents

If this Agreement is inconsistent with any other document or agreement between the parties, to the fullest extent permitted by law this Agreement prevails to the extent of the inconsistency.

13.4 Counterparts

This document may be executed in counterparts.

 $\boldsymbol{EXECUTED}$ as an agreement

us un agreement	
EXECUTED by pSivida Limited ACN 009 232 026:	
	/s/ Lori Freedman
	Signature of director/secretary
	Lori Freedman, VP, Corporate Affairs, General Counsel and Company Secretary
	Name
EXECUTED by Sol Capital Pty Ltd , by its sole director and sole company secretary:	/s/ Aaron Finlay
	Signature of sole director and sole company secretary
	Aaron Finlay
	Name

Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, Paul Ashton, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q 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 registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: May 12, 2008

/s/ Paul Ashton

Name: Paul Ashton
Title: Managing Director

Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

CERTIFICATIONS

I, Michael J. Soja, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q 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 registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: May 12, 2008

/s/ Michael J. Soja

Name: Michael J. Soja

Title: Vice President, Finance and Chief Financial Officer

Certification of Principal 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 Quarterly Report of pSivida Limited (the "Company") on Form 10-Q for the quarter ended March 31, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Ashton, Managing Director of the Company, certify that to the best of my knowledge:

- 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 results of operations of the Company.

Date: May 12, 2008

/s/ Paul Ashton

Name: Paul Ashton Title: Managing Director

Certification of Principal Financial 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 Quarterly Report of pSivida Limited (the "Company") on Form 10-Q for the quarter ended March 31, 2008, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael J. Soja, Vice President, Finance and Chief Financial Officer of the Company, certify that to the best of my knowledge:

- 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 results of operations of the Company.

Date: May 12, 2008

/s/ Michael J. Soja

Name: Michael J. Soja

Title: Vice President, Finance and Chief Financial Officer