# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

#### X QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2009

OR

#### TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF п 1934

For the transition period from

**COMMISSION FILE NUMBER 000-51122** 



(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

to

**400 Pleasant Street** Watertown, MA (Address of principal executive offices)

26-2774444 (I.R.S. Employer Identification No.)

> 02472 (Zip Code)

(617) 926-5000 (Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  $\Box$  No  $\Box$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer 

Non-accelerated filer

accelerated filer		Accelerated filer	
ccelerated filer		Smaller reporting company	X
Indicate by check n	nark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).	Yes 🗆 No 🗵	

There were 18,262,345 shares of the registrant's common stock, \$0.001 par value, outstanding as of May 11, 2009.

# PSIVIDA CORP. AND SUBSIDIARIES INDEX TO FORM 10-Q

PART I: U	UNAUDITED FINANCIAL INFORMATION	Page
Item 1.	Condensed Consolidated Financial Statements (unaudited)	
	Condensed Consolidated Balance Sheets – March 31, 2009 and June 30, 2008	3
	Condensed Consolidated Statements of Operations – Three and Nine Months Ended March 31, 2009 and 2008	4
	Condensed Consolidated Statement of Stockholders' Equity – Nine Months Ended March 31, 2009	5
	Condensed Consolidated Statements of Cash Flows – Nine Months Ended March 31, 2009 and 2008	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	25
Item 4.	Controls and Procedures	26
PART II:	OTHER INFORMATION	
Item 1A.	Risk Factors	27
Item 6.	<u>Exhibits</u>	27
Signature	<u>s</u>	28
<u>Certificati</u>	<u>ions</u>	

# PART I. UNAUDITED FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

# PSIVIDA CORP. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited) (In thousands except share amounts)

Current assets:         5         8,019         \$         15,000           Note receivable, not of allowance		March 31, 2009	June 30, 2008
Cash and cash equivalents       \$ 8,019       \$ 15,000         Note receivable, net of allowance	Assets		
Note receivable, net of allowance         —         481           Accounts and other receivables         879         986           Prepaid expenses and other current assets         469         614           Total current assets         9,367         17.690           Note receivable and other, net of allowance         133         815           Propeid agents, net         75         473           Thrangible assets, net         26.796         36.807           Current liabilities and stockholders' equity         \$ 36.371         \$ 5.784           Current liabilities and stockholders' equity         \$ 36.371         \$ 5.784           Current liabilities         \$ 36.371         \$ 5.784           Corrent revenue         \$ 40.93         \$ 1.933         \$ 2.236           Deferred revenue         \$ 4.013         \$ 8.114         \$ 7.767 <tr< td=""><td>Current assets:</td><td></td><td></td></tr<>	Current assets:		
Accounts and other receivables       879       986         Prepaid expenses and other current assets       469       614         Cotal current assets       9,367       17,600         Note receivable and other, net of allowance       133       819         Property and equipment, net       75       473         Intangible assets, net       26,796       36,802         Cotal assets       \$ 36,371       \$ 55,784         Liabilities and stockholders' equity       75       473         Current Liabilities:       1,533       2,233         Deferred revenue       8,649       1,533       2,233         Deferred revenue       8,654       10,477       10,477         Deferred revenue       8,654       10,477       10,477         Deferred revenue       8,654       10,477       11,018       17,276         Deferred revenue       4,013       8,114       11,018       17,276         Deferred revenue       4,013       8,114       12,257,068       31,284       25,706         Stockholders' equity       15,284       25,706       31,680       31,680       31,680       31,680       31,680       31,680       31,680       31,680       31,680       31,680		\$ 8,019	\$ 15,609
Prepaid expenses and other current assets	·	—	481
Total current assets         9,367         17,690           Note receivable and other, net of allowance         133         819           Property and equipment, net         75         477           intangible assets, net         26,796         36,802           Total assets         \$ 36,371         \$ 55,784           Liabilities and stockholders' equity         5         419         \$ 2,634           Current liabilities:			986
Note receivable and other, net of allowance       133       819         Property and equipment, net       75       473         intangible assets, net       26,796       36,802         Total assets       \$ 36,371       \$ 55,784         Liabilities and stockholders' equity       5       36,371       \$ 2,634         Current liabilities:	Prepaid expenses and other current assets	469	614
Property and equipment, net         75         473           Intangible assets, net         26,796         36,802           Total assets         \$ 36,371         \$ 5,784           Liabilities and stockholders' equity	Total current assets	,	17,690
margible assets, net       _26,796       _36,802         Total assets       \$ 36,371       \$ 55,784         Liabilities and stockholders' equity			819
Total assets         36,371         \$ 55,784           Liabilities and stockholders' equity         -		-	473
Liabilities and stockholders' equity Current liabilities: Accounts payable Accounts payable Accounts payable Accounts payable Accounts payable Account payable Accounts payable Account payabl	Intangible assets, net	26,796	36,802
Current liabilities:       \$ 419       \$ 2,634         Accounts payable       \$ 1,593       2,236         Accrued expenses       1,593       2,236         Deferred revenue       8,654       10,476         Derivative liabilities       352       1,930         Total current liabilities       11,018       17,276         Deferred revenue       4,013       8,114         Deferred tax liabilities       15,284       25,706         Stockholders' equity:       15,284       25,706         Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2009       18       18         Additional paid-in capital       248,200       247,628       247,628         Accumulated other comprehensive (loss) income       (21,087       30,078	Total assets	\$ 36,371	\$ 55,784
Accounts payable       \$ 419       \$ 2,634         Accound expenses       1,593       2,236         Deferred revenue       8,654       10,476         Derivative liabilities       352       1,930         Fotal current liabilities       11,018       17,276         Deferred revenue       4,013       8,114         Deferred tax liabilities       253       316         Fotal liabilities       15,284       25,706         Stockholders' equity:       15,284       25,706         Preferred stock, \$.001 par value, 5,000,000 shares authorized, 18,262,345 shares issued and outstanding at March 31, 2009	Liabilities and stockholders' equity		
Accrued expenses1,5932,236Deferred revenue8,65410,476Derivative liabilities3521,930Total current liabilities11,01817,276Deferred revenue4,0138,114Deferred tax liabilities253316Total liabilities253316Total liabilities15,28425,706Stockholders' equity:15,28425,706Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstandingCommon stock, \$.001 par value, 6,0,000,000 shares authorized, name issued and outstanding at March 31, 2009 and June 30, 20081818Additional paid-in capital248,200247,622Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,969Fotal stockholders' equity21,08730,076	Current liabilities:		
Deferred revenue       8,654       10,476         Derivative liabilities       352       1,930         Fotal current liabilities       11,018       17,276         Deferred revenue       4,013       8,114         Deferred tax liabilities       253       316         Fotal liabilities       253       316         Fotal liabilities       15,284       25,706         Stockholders' equity:       15,284       25,706         Common stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding       -       -         Common stock, \$.001 par value, 60,000,000 shares authorized, 18,262,345 shares issued and outstanding at March 31, 2009       18       18         Additional paid-in capital       248,200       247,622         Accumulated deficit       (226,514)       (224,537         Accumulated other comprehensive (loss) income       (617)       6,969         Fotal stockholders' equity       21,087       30,076		4 -	
Derivative liabilities3521,930Total current liabilities11,01817,276Deferred revenue4,0138,114Deferred tax liabilities253316Total liabilities15,28425,706Stockholders' equity:Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2009 and June 30, 20081818Additional paid-in capital248,200247,628Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,966Total stockholders' equity21,08730,078			2,236
Total current liabilities11,01817,276Deferred revenue4,0138,114Deferred tax liabilities253316Total liabilities15,28425,706Stockholders' equity:15,28425,706Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstandingCommon stock, \$.001 par value, 60,000,000 shares authorized, 18,262,345 shares issued and outstanding at March 31, 2009 and June 30, 20081818Additional paid-in capital248,200247,626247,626Accumulated deficit(226,514)(224,537)(224,537)Accumulated other comprehensive (loss) income6176,966Fotal stockholders' equity21,08730,076			10,476
Deferred revenue4,0138,114Deferred tax liabilities253316Total liabilities15,28425,706Stockholders' equity:15,28425,706Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2009 and June 30, 20081818Additional paid-in capital248,200247,6226Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,966Fotal stockholders' equity21,08730,076	Derivative liabilities	352	1,930
Deferred tax liabilities 253 316 Total liabilities 15,284 25,706 Stockholders' equity: Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding and June 30, 2008 — — — Additional paid-in capital 248,200 247,628 Accumulated deficit (226,514) (224,537 Accumulated other comprehensive (loss) income (	Total current liabilities	11,018	17,276
Total liabilities15,28425,706Stockholders' equity: Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding and June 30, 2008——Additional paid-in capital Accumulated deficit Accumulated other comprehensive (loss) income1818Item comprehensive (loss) income(617)6,965Total stockholders' equity21,08730,078	Deferred revenue	4,013	8,114
Stockholders' equity:       Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding       —       …<	Deferred tax liabilities	253	316
Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding——Common stock, \$.001 par value, 60,000,000 shares authorized, 18,262,345 shares issued and outstanding at March 31, 20091818and June 30, 200818248,200247,622Additional paid-in capital248,200247,622Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,965Total stockholders' equity21,08730,078	Total liabilities	15,284	25,706
Common stock, \$.001 par value, 60,000,000 shares authorized, 18,262,345 shares issued and outstanding at March 31, 20091818and June 30, 200818248,200247,628Additional paid-in capital248,200247,628Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,969Total stockholders' equity21,08730,078	Stockholders' equity:		
and June 30, 20081818Additional paid-in capital248,200247,628Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,969Total stockholders' equity21,08730,078	Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding	_	_
Additional paid-in capital248,200247,628Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,969Total stockholders' equity21,08730,078	Common stock, \$.001 par value, 60,000,000 shares authorized, 18,262,345 shares issued and outstanding at March 31, 2009		
Accumulated deficit(226,514)(224,537Accumulated other comprehensive (loss) income(617)6,965Total stockholders' equity21,08730,078		18	18
Accumulated other comprehensive (loss) income(617)6,969Total stockholders' equity21,08730,078			247,628
Total stockholders' equity 21,087 30,078			
	Accumulated other comprehensive (loss) income	(617)	6,969
Fotal liabilities and stockholders' equity\$ 36,371\$ 55,784	Total stockholders' equity	21,087	30,078
	Total liabilities and stockholders' equity	\$ 36,371	\$ 55,784

3

See notes to condensed consolidated financial statements

# PSIVIDA CORP. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited) (In thousands except per share amounts)

		Three Months Ended March 31,				
	2009	2008	2009	2008		
Revenues:	¢ 0.400	<b>* =</b> 00	<b>*</b> • • • • •	<b>*</b>		
Collaborative research and development	\$ 3,136	\$ 503	\$ 8,816	\$ 681		
Royalty income	27	39	123	92		
Total revenues	3,163	542	8,939	773		
Operating expenses:						
Research and development	1,892	3,605	6,177	12,022		
General and administrative	2,052	3,546	7,343	8,609		
Total operating expenses	3,944	7,151	13,520	20,631		
Loss from operations	(781)	(6,609)	(4,581)	(19,858)		
Other income (expense):						
Change in fair value of derivatives	22	1,172	1,578	7,193		
Interest income	22	121	155	534		
Interest expense	_	(206)	_	(507)		
Other (expense) income, net	(4)	6	7	308		
Total other income	40	1,093	1,740	7,528		
Loss before income taxes	(741)	(5,516)	(2,841)	(12,330)		
Income tax benefit	105	15	864	239		
Net loss	<u>\$ (636)</u>	<u>\$ (5,501)</u>	<u>\$ (1,977)</u>	\$(12,091)		
Basic and diluted net loss per share	<u>\$ (0.03)</u>	\$ (0.30)	\$ (0.11)	<b>\$ (0.67</b> )		
Weighted average common shares outstanding:						
Basic and diluted	18,262	18,260	18,262	18,134		

See notes to condensed consolidated financial statements

# PSIVIDA CORP. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited)

(In thousands, except share amounts)

	Common	Stock	Additional		Accumulated Other	Total
	Number of Shares	Par Value Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity
Balance at July 1, 2008	18,262,345	\$ 18	\$247,628	\$ (224,537)	\$ 6,969	\$ 30,078
Comprehensive loss:						
Net loss		—		(1,977)	—	(1,977)
Foreign currency translation adjustments	—	—	—	—	(7,586)	(7,586)
Total comprehensive loss						(9,563)
Stock-based compensation			572			572
Balance at March 31, 2009	18,262,345	<u>\$ 18</u>	\$248,200	\$ (226,514)	\$ (617)	\$ 21,087

See notes to condensed consolidated financial statements

# PSIVIDA CORP. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

		ths Ended ch 31,
	2009	2008
Cash flows from operating activities:		
Net loss	\$ (1,977)	\$(12,091
Adjustments to reconcile net loss to cash flows from operating activities:		
Amortization of intangible assets	2,525	2,926
Depreciation of property and equipment	89	320
Change in fair value of derivatives	(1,578)	(7,193
Provision for losses on note receivable	1,300	
Stock-based compensation expense	572	148
Deferred income tax benefit	(63)	(239
Loss on sale of equipment	39	—
Non-cash interest expense		507
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	2	(1,201
Accounts payable and accrued expenses	(2,581)	(4,655
Deferred revenue	(5,624)	18,775
let cash used in operating activities	(7,296)	(2,703
Cash flows from investing activities:		
Purchases of property and equipment	(174)	(133
Net cash used in investing activities	(174)	(133
Cash flows from financing activities:		
Proceeds from issuance of shares	<u> </u>	20,622
Share issue costs		(2,235
Net cash provided by financing activities		18,387
Effect of foreign exchange rate changes on cash and cash equivalents	(120)	(46
Net (decrease) increase in cash and cash equivalents	(7,590)	15,505
Cash and cash equivalents at beginning of period	15,609	2,670
Cash and cash equivalents at end of period	\$ 8,019	\$ 18,175

6

See notes to condensed consolidated financial statements

## PSIVIDA CORP. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

#### 1. Operations and Basis of Presentation

The accompanying condensed consolidated financial statements of pSivida Corp. and subsidiaries (the "Company") for the three and nine months ended March 31, 2009 and 2008 are unaudited. Certain information in the footnote disclosures of these financial statements has been condensed or omitted in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC"). These financial statements should be read in conjunction with the Company's audited consolidated financial statements and footnotes included in its Annual Report on Form 10-K for the fiscal year ended June 30, 2008. The balance sheet amounts at June 30, 2008 in this report were derived from the Company's audited financial statements. In the opinion of management, these statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended June 30, 2008, and include all adjustments that are necessary for the fair presentation of the Company's financial position, results of operations and cash flows for the periods indicated. The preparation of financial statements in accordance with generally accepted accounting principles requires management to make assumptions and estimates that affect, among other things, (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 revenues and expenses during the reporting period. The results of operations for the three and nine months ended March 31, 2009 are not necessarily indicative of the results that may be expected for the entire year or any future period.

pSivida Corp. develops miniaturized, injectable, drug delivery systems. The Company's lead development product, Iluvien<sup>™</sup>, delivers fluocinolone acetonide ("FA") for the treatment of diabetic macular edema ("DME"). Formerly known as Medidur<sup>™</sup> FA for DME, Iluvien is in fully recruited Phase III clinical trials. The Company has licensed certain of its drug delivery technology to Alimera Sciences ("Alimera") for the development of Iluvien and certain other ophthalmic products. The Company also has two products approved by the Food and Drug Administration ("FDA"): Retisert® for the treatment of uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus ("CMV") retinitis. The Company has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated ("Bausch & Lomb"). The Company has a worldwide collaborative research and license agreement with Pfizer, Inc. ("Pfizer") under which Pfizer may develop additional ophthalmic products.

The Company owns the rights to develop and commercialize a modified form of silicon known as BioSilicon<sup>™</sup>, which has potential therapeutic applications. The most advanced BioSilicon product candidate, BrachySil<sup>™</sup>, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. The Company has completed an initial safety and efficacy clinical trial of BrachySil for the treatment of pancreatic cancer and has completed enrollment of a follow-on dose-ranging clinical trial.

Throughout this quarterly report on Form 10-Q, references to "\$" are to U.S. dollars and references to "A\$" are to Australian dollars.

#### **Business Risks and Uncertainties**

The Company's prospects, and ultimately its ability to achieve success, including profitable operations, are subject to risks and uncertainties that include, but are not limited to, maintaining its key collaboration agreements with Alimera and Pfizer; uncertainties regarding the achievement of milestones and other contingent contractual payment events; failure to prove safety and efficacy of Iluvien or BrachySil; inability to raise capital; continued losses and lack of profitability; inability to derive revenues from Retisert; termination of license agreements; inability to pay any registration penalties; 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; competition; risks and costs of international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; impairment of intangibles; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; and possible influence by Pfizer. The Company cannot be certain that it will be able to maintain its existing collaboration agreements, achieve additional collaboration arrangements or obtain other sources of funding, if and when needed, on acceptable terms, or at all, or that the Company will be able to achieve revenues sufficient for profitable operations.

## Liquidity

Cash and cash equivalents totaled approximately \$8.0 million at March 31, 2009 compared to \$15.6 million at June 30, 2008. The Company believes that it can fund its operations as currently conducted through at least December 31, 2010. This expectation is based on the assumptions that the Company continues to receive the Pfizer quarterly \$500,000 research and development funding, Alimera continues to fund the development of Iluvien, the Company resumes receiving Retisert royalties from Bausch & Lomb prior to June 30, 2010 and the Company continues to receive the scheduled conditional note payments from Alimera. However, whether and when the Company will require or desire to raise additional capital will depend upon many other factors, including, but not limited to:

- the continuation of the Company's collaborations with Pfizer and Alimera on their existing terms, including the continued funding by Pfizer and Alimera of the Company's programs and the receipt of applicable milestone, royalty, note and other payments, and the ability of Pfizer and Alimera to finance such funding and payments;
- the development, regulatory approval and commercialization of Iluvien, which is the Company's primary product candidate currently in development;
- the amount and timing of sales of Retisert, which affect the timing of the resumption of Retisert royalty payments and the amount of such royalty payments;
- the scope and extent of the Company's internally funded operations, including its programs for BrachySil (including any Phase III clinical trials for BrachySil for pancreatic cancer), any new product candidates, or any new business opportunities;
- the Company's ability to establish and maintain strategic arrangements for Brachysil or any other product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of the Company's 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; and
- changes in the Company's operating plan, including the pursuit of new business opportunities, which may affect its need for capital.

The Company's future cash position beyond December 31, 2010 depends significantly on the regulatory approval and marketing of Iluvien. Alimera has agreed to pay the Company \$25.0 million upon FDA approval of Iluvien and a 20% share in the future profits of Iluvien. There is no assurance that the FDA will approve Iluvien or that Iluvien will achieve market acceptance even if it is approved by the FDA.

## **Recently Adopted Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("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, for purposes such as derivative valuation and impairment analysis, and expands disclosures about fair value measurements. Under the standard, fair value measurements are to be separately disclosed by level within a fair value hierarchy. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. Pursuant to FASB Staff Position ("FSP") No. 157-2, issued in February 2008, the application of SFAS 157 for nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in financial statements on a non-recurring basis may be deferred until fiscal years beginning after November 15, 2008. The Company adopted SFAS 157 as of July 1, 2008, with the exception of the application of the statement to non-recurring nonfinancial liabilities. See Note 11 for additional details.

In July 2008, the Company adopted SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities* — *Including an Amendment of FASB Statement No. 115*" ("SFAS 159"). SFAS 159 permits companies to choose to measure selected financial assets and liabilities at fair value, with changes in fair value recognized in earnings each reporting period. Prior to July 2008, the Company recorded derivative liabilities at fair value in accordance with SFAS No. 133, "*Accounting for Derivative Instruments and Hedging Activities*", as amended. The adoption of SFAS 159 had no impact on the Company's consolidated financial position and results of operations as management did not elect the fair value option for any other financial assets and liabilities.

In June 2007, the FASB issued Emerging Issues Task Force ("EITF") Issue No. EITF 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-03"), which requires nonrefundable advance payments for future research and development activities to be capitalized and recognized as an expense as the goods are delivered or the related services are performed. The Company adopted EITF 07-03 as of July 1, 2008 and the adoption did not have any impact on its consolidated financial statements.

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"). SFAS 161 amends and expands the disclosure requirements for derivative instruments and hedging activities, with the intent to provide users of financial statements with an enhanced understanding of (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under FASB Statement No. 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity's financial statements. The Company adopted SFAS 161 on January 1, 2009. See Notes 2, 6 and 11 for the Company's disclosures about its derivative liabilities.

## **Recently Issued Accounting Pronouncements**

In November 2007, the FASB issued EITF Issue No. 07-01, "Accounting for Collaborative Arrangements" ("EITF 07-01"). EITF 07-01 defines a collaborative arrangement as a contractual arrangement in which the parties are (i) active participants to the arrangement; and (ii) exposed to significant risks and rewards that depend upon the commercial success of the endeavor. It also addresses the appropriate statement of operations presentation for activities and payments between the participants in a collaborative arrangement as well as for costs incurred and revenue generated from transactions with third parties. EITF 07-01 will be effective for the Company's fiscal year beginning July 1, 2009. The Company is evaluating the potential impact of adopting EITF 07-01 on its consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised), "Business Combinations" ("SFAS 141R"), which provides revised guidance for recognition and measurement of identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree at fair value. SFAS 141R 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 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is required to be applied 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. The Company will be required to adopt SFAS 141R in connection with business combination transactions, if any, after June 30, 2009.

In April 2008, the FASB issued FSP No. 142-3, "*Determination of the Useful Life of Intangible Assets*" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "*Goodwill and Other Intangible Assets*" ("SFAS 142"). The objective of FSP 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R and other accounting principles. FSP 142-3 applies to all intangible assets, whether acquired in a business combination or otherwise, and early adoption is prohibited. The Company will be required to adopt FSP 142-3 for its fiscal year beginning July 1, 2009. The Company is evaluating the potential impact of adopting FSP 142-3 on its consolidated financial statements.

## 2. 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 3,600,500 units at a price of \$5.00 per unit for gross proceeds of \$18.0 million. Each unit consisted of (i) one common share; and (ii) one warrant to purchase 0.4 common share, with a warrant exercise price of \$6.60 per share. Of the total, 1,300,000 units were purchased by Pfizer in accordance with the terms of the Collaborative Research and License Agreement dated April 3, 2007. A total of 72,010 warrants, with a warrant exercise price of \$6.60, were issued to the placement agents in connection with the offering. In addition, the Company simultaneously completed a sale of common shares and warrants at the equivalent price of A\$5.84 per unit under the same terms and conditions noted above. This sale of 513,699 units resulted in additional gross proceeds of approximately \$2.6 million. Aggregate share issue costs for these transactions totaled approximately \$2.2 million.

## Warrants to Purchase Common Shares

At March 31, 2009, the Company had outstanding warrants to purchase common shares that were denominated in \$ with a weighted average remaining life at March 31, 2009 of 2.9 years, as follows:

	Nine Months Ended March 31,				
	200	9	200	2008	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price	
Balance at beginning of period	7,195,498	\$ 7.69	5,683,288	\$ 8.00	
Granted	—	—	1,512,210	6.60	
Expired	(33,250)	50.00			
Balance and exercisable at end of period	7,162,248	\$ 7.50	7,195,498	\$ 7.69	

At March 31, 2009, the Company had outstanding warrants to purchase common shares that were denominated in A\$ with a weighted average remaining life at March 31, 2009 of 2.0 years, as follows:

	Nine Months	Nine Months Ended March 31,			
	2009	200	2008		
	Weighte Averag Number of Exercis Warrants Price A\$	<u>!</u>	Weighted Average Exercise <u>Price</u> A\$		
Balance at beginning of period	3,986,683 9.9	3,781,204	10.11		
Granted		205,479	7.68		
Expired	(51,250) 43.6	)			
Balance and exercisable at end of period	3,935,433 9.5	4 3,986,683	9.98		

At March 31, 2009 and 2008, the weighted average exercise price of these warrants translated to \$ was \$6.52 and \$9.16, respectively.

## 3. License and Collaboration Agreements

The Company has collaborative license and development agreements 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 and sales milestones, and royalties in the form of a designated percentage of product sales or profits. Multiple element 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 No. 00-21, "Accounting for Revenue Arrangements with Multiple Deliverables".

For arrangements that are accounted for as a single unit of accounting, payments under the arrangement 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 obligations either cease or become inconsequential, then

revenue recognition is deferred until the Company can reasonably estimate when the performance obligations cease or become inconsequential. 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.

The Company's significant license and collaboration agreements are summarized below.

#### Alimera Sciences, Inc.

In March 2008, the Company and Alimera amended and restated their February 2005 license and collaboration agreement relating to Iluvien (the "Alimera Agreement"), 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, the Company decreased its share in the future profits of Iluvien from 50% to 20%.

Consideration received at closing consisted of (i) \$12.0 million in cash 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 Agreement ends December 31, 2009. Accordingly, from 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, is being 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 due upon FDA approval of Iluvien; and (iii) the assumption by Alimera of all financial responsibility for the development of licensed products under the collaboration agreement, including reimbursement of approved development costs incurred by the Company in support of the ongoing clinical studies of Iluvien and anticipated regulatory submissions. All 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.

For the three and nine months ended March 31, 2009, revenue related to the Alimera Agreement totaled \$3.0 million and \$8.7 million, respectively, which represented substantially all of the Company's collaborative research and development revenue for these periods.

#### Pfizer

In April 2007, the Company and Pfizer entered into a Collaborative Research and License Agreement (the "Pfizer Agreement"), which superseded a December 2006 research agreement. Under the Pfizer Agreement, the parties have implemented a joint research program aimed at developing certain ophthalmic products using the Company's Durasert<sup>TM</sup> drug delivery technology. In addition to potential development and sales related milestone payments, Pfizer pays the Company a minimum of \$500,000 per quarter in consideration of the Company's costs in performing the research program. These payments commenced in calendar year 2008 and continue until the earlier of the commencement of the first Phase III clinical trial for a licensed product candidate or the termination of the Agreement.

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 evaluating the timing of the deliverables and other obligations under the Pfizer Agreement and, as a result, all payments received from Pfizer through March 31, 2009, totaling \$3.2 million, have been classified in deferred revenue as a non-current liability.

## Intrinsiq

In January 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 \$1.2 million. In addition, subject to Intrinsiq's unilateral right to terminate the license upon 90 days prior written notice, Intrinsiq will be obligated to pay the Company aggregate minimum royalties of \$3.55 million through April 2014, of which the first \$450,000 payment is due in July 2009.

Under the original agreement, the parties were obligated to enter into a manufacture and supply agreement, which was consummated effective as of February 1, 2009. Pursuant to the supply agreement, the Company leased to Intrinsiq certain equipment for its use in manufacturing BioSilicon material. Subject to its right to terminate the lease, Intrinsiq will acquire title to the equipment upon the remittance of lease payments totaling \$122,000 over the 2-year lease term.

The Company has determined that the equipment lease component represents a separate element of this arrangement to be accounted for in accordance with SFAS No. 13, "*Accounting for Leases*". Using the relative fair value method prescribed under EITF 00-21, the Company allocated the arrangement consideration between the lease and license deliverables. The Company has determined the performance period of the license arrangement to be 17 years, coinciding with the last to expire of the patents licensed to Intrinsiq, and is recognizing consideration allocated to the license arrangement on a straight-line basis over this period. During the three months ended March 31, 2009, the Company recognized approximately \$63,000 of collaborative research and development revenue, and the remaining balance of payments received of \$815,000 has been recorded as deferred revenue at March 31, 2009.

#### 4. Intangible Assets

A summary of intangible assets at March 31, 2009 and June 30, 2008 is as follows:

	 Months Ended r <u>ch 31, 2009</u> (In thousands	Year Ended June 30, 2008
Patents and licences		
Gross carrying amount at beginning of period	\$ 64,342	\$ 64,534
Foreign currency translation adjustments	(13,009)	(192)
Gross carrying amount at end of period	 51,333	64,342
Accumulated amortization at beginning of period	(27,540)	(23,732)
Amortization expense	(2,525)	(3,886)
Foreign currency translation adjustments	5,528	78
Accumulated amortization at end of period	 (24,537)	(27,540)
Net book value at end of period	\$ 26,796	\$ 36,802

Amortization of intangible assets totaled \$772,000 and \$2.5 million for the three and nine month periods ended March 31, 2009, respectively and \$962,000 and \$2.9 million for the three and nine month periods ended March 31, 2008, respectively. The carrying value of intangible assets at March 31, 2009 of \$26.8 million will be amortized on a straight-line basis over the remaining estimated useful life of 8.75 years. Of the total net book value at March 31, 2009, approximately \$9.2 million was attributable to the Retisert product and \$17.6 million was attributable to the BioSilicon technology.

#### 5. Note Receivable

The Company has an outstanding note receivable from GEM Global Yield Fund ("GEM"), issued in connection with the fiscal year 2007 sale of a former wholly-owned subsidiary, that matured on April 12, 2008. During the fourth quarter of fiscal 2008, the Company demanded payment of the note and, based upon initial negotiations, the Company reduced the carrying value of the note and accrued interest by \$325,000 to its estimated net realizable value of \$1.3 million at June 30, 2008. As a result of ongoing negotiations, the Company reduced the carrying value of the note to \$667,000 at September 30, 2008. At December 31, 2008, based upon the Company's inability to reach agreement with GEM after further discussions, the Company recorded a charge to operations for the remaining carrying value of the note. The provision for losses on the note receivable of \$1.3 million for the nine months ended March 31, 2009 was included in general and administrative expense in the condensed consolidated statements of operations.

## 6. Derivative Liabilities

In connection with several capital raising transactions during the years ended June 30, 2008 and 2007, the Company issued units consisting of common shares together with detachable warrants to purchase additional common shares over a specified time period. In certain of these transactions, the warrants were denominated in A\$, which is different than the

Company's \$ functional currency. To the extent that the potential exercise of such warrants would result in a variable amount of proceeds in the Company's functional currency, the fair value of the warrants was recorded as a derivative liability, with a corresponding reduction in additional paid-in capital, subject to revaluation of the liability on a marked-to-market basis through profit and loss. The fair value of the warrants was determined using a Black-Scholes model. The net reduction in the fair values of these derivative liabilities for the three and nine months ended March 31, 2009 resulted in income recognized of \$22,000 and \$1.6 million, respectively, compared to income recognized of \$1.2 million and \$7.2 million for the three and nine months ended March 31, 2008, respectively. The primary factor impacting the change in the fair value of these derivatives is the Company's share price. A 10 percent increase or decrease in the Company's share price at March 31, 2009 would cause a \$84,000 increase or \$75,000 decrease in the derivative liabilities, respectively.

#### 7. Stock-Based Compensation

The Company records compensation cost on a straight-line basis over the award's requisite service period for all share-based awards granted. Grant date fair value of stock option awards (less estimated forfeitures) is determined using the Black-Scholes option valuation model.

#### **Employee Share Option Plan**

The Company's Employee Share Option Plan (the "Plan") provided for the issuance of non-qualified stock options to eligible employees and directors. Option grants under the Plan have requisite service periods ranging from immediate vesting to 3-year ratable annual vesting, a contractual life of five years and are denominated in A\$. As of June 2008, no further options will be granted under the Plan.

During the nine months ended March 31, 2008, 136,250 options were granted under the Plan. The exercise prices of all outstanding options under the Plan at March 31, 2009 were in excess of the market price of the Company's common shares at that date and, accordingly, the options had an aggregate intrinsic value of \$0. A total of 17,552 and no options vested during the three months ended March 31, 2009 and 2008, respectively. At March 31, 2009, there were 419,241 options vested or expected to vest in the future, with an aggregate intrinsic value of \$0 and a weighted-average remaining contractual term of 1.56 years.

The following table provides a reconciliation of stock option activity under the Plan for the nine months ended March 31, 2009:

	Number of Options	Weighted Average Exercise Price A\$	Remaining Contractual Life (in years)
Outstanding at June 30, 2008	455,478	29.57	
Forfeited	(3,334)	5.50	
Cancelled	(27,361)	40.65	
Outstanding at March 31, 2009	424,783	29.05	1.55
Exercisable at March 31, 2009	328,064	34.40	1.09

At March 31, 2009 the weighted average exercise prices of outstanding and exercisable options translated into \$ were \$19.86 and \$23.51, respectively.

## 2008 Incentive Plan

The pSivida Corp. 2008 Incentive Plan (the "2008 Plan") provides for the issuance of a maximum of 1,750,000 common shares in stock-based awards to management, other key employees, consultants and directors. No options were granted during the three months ended March 31, 2009. A total of 1,221,000 options were granted during the nine months ended March 31, 2009, with ratable annual vesting periods ranging from 1 to 4 years and a 10-year life.

The Company measures the fair value of options on their grant date using the Black-Scholes option-pricing model. Based upon limited option exercise history, the Company has used the "simplified" method outlined in SEC Staff Accounting Bulletin No. 107 to estimate the expected life of stock option grants. Expected volatility is based on historical volatility of our stock over the expected life of the option. The risk-free interest rate is based on the weighted-average of U.S. Treasury rates over the expected life of the stock option.

Key weighted average assumptions used to apply this option pricing model to the 2008 Plan were as follows:

	Nine Months Ended March 31, 2009
Option life (in years)	6.09
Stock volatility	85%
Risk-free interest rate	2.78%
Expected dividends	0%

The following table provides a reconciliation of stock option activity under the 2008 Plan for the nine months ended March 31, 2009:

	Number of Options	Weighted Average Exercise Price	Remaining Contractual Life (in years)
Outstanding at June 30, 2008	—	\$ —	,
Granted	1,221,000	1.98	
Outstanding at March 31, 2009	1,221,000	\$ 1.98	8.78
Exercisable at March 31, 2009	110,000	\$ 2.89	0.97

For option grants to non-executive employees, an estimated annual forfeiture rate of 5% per year was used to determine awards expected to vest and to calculate stock-based compensation. 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.

Estimates of fair value may not represent actual future events or the value to be ultimately realized by persons who receive stock option awards.

The weighted average grant date fair value of stock options granted pursuant to the 2008 Plan for the nine months ended March 31, 2009 was \$1.43. The exercise prices of all outstanding options under the 2008 Plan at March 31, 2009 are in excess of the market price of the Company's common shares at that date and, accordingly, the options have an aggregate intrinsic value of \$0. A total of 110,000 options vested during the three months ended March 31, 2009. These options vested pursuant to the terms of a March 2009 severance agreement with the Company's former Vice President, Finance and Chief Financial Officer, and expire in March 2010. At March 31, 2009, there were 1,175,653 options vested or expected to vest in the future with an aggregate intrinsic value of \$0 and a weighted-average remaining contractual term of 8.8 years.

## Nonvested Stock Issued to CDS Employees

On December 30, 2005, the Company issued 224,798 nonvested common shares with a fair value of \$26.40 per common share to employees of Control Delivery Systems, Inc. ("CDS") in exchange for their nonvested CDS stock. The portion of the fair value attributable to the employees' pre-acquisition service period was included as part of the CDS acquisition cost and the value attributable to the post-acquisition service period was ratably expensed over the vesting period.

The following table presents a reconciliation of the activity related to the issuance of these nonvested common shares:

	Year Ended June 30, 2008
Balance at beginning of year	8,587
Vested	(8,587)
Forfeited	—
Balance at end of year	

#### Stock-Based Compensation Expense

Stock-based compensation expense related to the Company's stock option plans, including amortization of nonvested common shares, was charged to operations for the three and nine month periods ended March 31, 2009 and 2008, as follows:

	1				Nine Mo Ma	nths En rch 31,	ded
	—	Three Months Ended March 31,           2009         2008           (In the second		s 1 thousan	2009		2008
Research and development	\$	66	\$	4	\$ 147	\$	26
General and administrative		198	5	58	425		122
	\$	264	\$ 6	52	\$ 572	\$	148

At March 31, 2009, there was approximately \$1.1 million of unrecognized compensation expense, net of estimated forfeitures, related to nonvested stockbased payment awards under the Company's option plans. This compensation cost is expected to be recognized over a weighted average period of 2.0 years and will be adjusted for any future changes in estimated forfeitures.

## **Options Issued in Exchange for CDS Options**

On December 30, 2005, as part of the consideration for the acquisition of CDS, the Company issued 43,112 fully vested stock options with a fair value of \$15.48 per share in exchange for outstanding CDS options which were fully vested prior to or upon the acquisition. The following table presents a reconciliation of the activity related to the issuance of these options:

		Nine Months E	nded March 31,	
	200	09	200	8
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Balance at beginning of period	17,614	\$ 11.35	38,443	\$ 18.44
Expired			(19,375)	17.32
Balance outstanding and exercisable at end of period	17,614	\$ 11.35	19,068	\$ 19.60

The weighted average remaining contractual life of these exercisable options at March 31, 2009 was 0.5 year.

#### 8. Income Taxes

The Company applies SFAS No. 109, "Accounting for Income Taxes" ("SFAS 109"), which requires the Company to recognize deferred tax assets and liabilities for estimated future tax consequences of events that have been recognized in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax assets will not be realized. Because of the Company's historical losses from operations, a valuation allowance was established for the net deferred tax assets. During the three and nine months ended March 31, 2009, the Company recognized an income tax benefit of \$105,000 and \$864,000, respectively. The nine month period ended March 31, 2009 included a benefit of \$773,000 relating to prior and current years foreign research and development credits earned by its U.K. subsidiary. The income tax benefit was also positively impacted by approximately \$130,000 of provision adjustments associated with the filing of certain income tax returns during the quarter ended March 31, 2009.

The Company adopted FASB Interpretation ("FIN") No. 48, "*Accounting for Uncertainty in Income* Taxes" ("FIN 48") on July 1, 2007. The implementation of FIN 48 did not have any impact on the Company's consolidated financial position or results of operations. From adoption through March 31, 2009, the Company had no significant unrecognized tax benefits in the accompanying unaudited condensed consolidated financial statements. The Company does not expect that the amounts of unrecognized tax benefits will change significantly within the next 12 months or that future changes in unrecognized tax benefit will have a material impact on the Company's effective tax rate due to the existence of valuation allowances.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. As of March 31, 2009, the Company had no accrued penalties or interest related to uncertain tax positions.

## 9. Loss Per Share

Basic net loss per share was computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share was computed by dividing the net loss by the sum of (i) the weighted average number of common shares outstanding and (ii) the weighted average number of common shares that would be issued on the conversion of all dilutive securities outstanding. Potentially dilutive shares were not included in the calculation of diluted net loss per share for each of the three and nine month periods ended March 31, 2009 and 2008 as their inclusion would be anti-dilutive.

Potentially dilutive shares at March 31, 2009 and 2008 were as follows:

	Marc	h 31,
	2009	2008
Options	1,663,397	474,546
Warrants	11,097,681	11,182,181
Nonvested stock issued in connection with CDS acquisition		2,862
	12,761,078	11,659,589

## 10. Comprehensive Loss

Comprehensive loss for the three and nine month periods ended March 31, 2009 and 2008 was as follows:

		onths Ended rch 31,		Nine Months Ended March 31,	
	2009	2008	2009	2008	
		(In tho	usands)		
Net loss	\$ (636)	\$ (5,501)	\$(1,977)	\$(12,091)	
Foreign currency translation adjustments	(332)	(74)	(7,586)	(241)	
Comprehensive loss	<u>\$ (968)</u>	\$ (5,575)	\$(9,563)	\$(12,332)	

# 11. Fair Value Measurements

In September 2006, the FASB issued SFAS 157, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The Company adopted SFAS 157 on July 1, 2008. SFAS 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs, where available. The three levels of the fair value hierarchy are described as follows:

- Level 1 Inputs are quoted prices in active markets that are accessible at the measurement date for identical assets and liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2 Inputs are observable prices that are based on inputs not quoted on active markets, but corroborated by market data.
- Level 3 Inputs are unobservable inputs that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities. The fair value hierarchy gives the lowest priority to Level 3 inputs.

As of March 31, 2009, the Company's derivative liabilities were classified as Level 3. The Company valued the derivative liabilities using the Black-Scholes model, for which observable market inputs included the Company's share price, historical volatility and risk-free interest rate.

The following table summarizes the Company's assets and liabilities carried at fair value measured on a recurring basis at March 31, 2009 by valuation hierarchy:

	Va	Carrying lue at 1 31, 2009	active	l prices in markets evel 1)	nificant other ervable inputs (Level 2)	unobse	gnificant rvable inputs Level 3)
Derivative liabilities	\$	352	\$		\$ 	\$	352

The reconciliation of the Company's liabilities measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Li	erivative abilities housands)
Balance at July 1, 2008	\$	1,930
Change in fair value of derivatives - other income (expense)		1,578
Balance at March 31, 2009	\$	352

## 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 within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). We often, although not always, identify forward-looking statements by using words or phrases such as the following: "likely", "expect", "intend", "anticipate", "believe", "estimate", "plan", "project", "forecast" and "outlook".

The following are some of the factors that could cause actual results to differ materially from the forward-looking statements: maintaining key collaboration agreements with Alimera and Pfizer; modification of existing terms of key collaboration agreements with Alimera and Pfizer; uncertainties regarding the achievement of milestones and other contingent contractual payment events; failure to prove safety and efficacy of Iluvien or BrachySil; inability to raise capital; continued losses and lack of profitability; inability to derive revenue from Retisert; termination of license agreements; inability to pay any registration penalties; 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; competition; risks and costs of international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; impairment of intangibles; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; possible influence by Pfizer; and other factors that may be described in our filings with the Securities and Exchange Commission. Further information on these risk factors is included in Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended June 30, 2008. You should read and interpret any forward-looking statements together with these risks. Any forward-looking statement applies only as of the date on which that statement is made. 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 develop miniaturized, injectable, drug delivery systems. Our lead development product, Iluvien<sup>™</sup>, delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). Formerly known as Medidur<sup>™</sup> FA for DME, Iluvien is in fully recruited Phase III clinical trials. We have licensed certain of our drug delivery technology to Alimera Sciences, Inc. (Alimera) for the development of Iluvien and certain other ophthalmic products. We also have two products approved by the Food and Drug Administration (FDA): Retisert<sup>®</sup> for the treatment of uveitis and Vitrasert<sup>®</sup> for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated (Bausch & Lomb). We have a worldwide collaborative research and license agreement with Pfizer Inc. (Pfizer) under which Pfizer may develop additional ophthalmic products.

We own the rights to develop and commercialize a modified form of silicon known as BioSilicon<sup>™</sup>, which has potential therapeutic applications. Our most advanced BioSilicon product candidate, BrachySil<sup>™</sup>, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. We have completed an initial safety and efficacy clinical trial of Brachysil for the treatment of pancreatic cancer and have completed enrollment of a follow-on dose-ranging clinical trial.

BioSilicon<sup>™</sup>, BrachySil<sup>™</sup> and Medidur<sup>™</sup> are our trademarks. Retisert<sup>®</sup> and Vitrasert<sup>®</sup> are Bausch & Lomb's trademarks, and Iluvien<sup>™</sup> is Alimera's trademark.

## **Summary of Critical Accounting Policies**

The preparation of consolidated financial statements requires us to make 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. Critical accounting policies are those policies that affect our more significant judgments and estimates used in the preparation of our consolidated financial

statements. We believe that our critical accounting policies include our policies regarding revenue recognition for license agreements and valuation of long-lived assets, including intangibles. For a more detailed discussion of these critical accounting policies, please refer to our Annual Report on Form 10-K for the fiscal year ended June 30, 2008, as filed with the SEC.

## **Results of Operations**

Three Months Ended March 31, 2009 Compared to Three Months Ended March 31, 2008:

	Mar	nths Ended ch 31,	Chang	
	<u>2009</u>	2008 thousands excep	Amounts	%
Revenues	\$ 3,163	\$ 542	\$ 2,621	484%
Revenues	φ 5,105	φ 342	φ 2,021	40470
Operating expenses:				
Research and development	1,892	3,605	(1,713)	(48)%
General and administrative	2,052	3,546	(1,494)	(42)%
Total operating expenses	3,944	7,151	(3,207)	(45)%
Loss from operations	(781)	(6,609)	5,828	(88)%
Other income (expense):				
Change in fair value of derivatives	22	1,172	(1,150)	(98)%
Interest income	22	121	(99)	(82)%
Interest expense		(206)	206	(100)%
Other	(4)	6	(10)	(167)%
Total other income	40	1,093	(1,053)	(96)%
Loss before income taxes	(741)	(5,516)	4,775	(87)%
Income tax benefit	105	15	90	600%
Net loss	<u>\$ (636)</u>	\$ (5,501)	\$ 4,865	(88)%

### Revenues

Revenues increased by approximately \$2.6 million to \$3.2 million for the three months ended March 31, 2009 from \$542,000 for the three months ended March 31, 2008. The increase was attributable to revenue recognized in connection with the March 2008 amended collaboration agreement with Alimera.

The Company recorded approximately \$18.3 million of deferred revenue at the effective date of the Alimera amendment and has received additional cash consideration of approximately \$1.9 million through March 31, 2009. The \$8.5 million balance of deferred revenue at March 31, 2009 will be recognized as revenue ratably over the performance period through December 2009, or approximately \$2.8 million per quarter. Future cash consideration received by the Company pursuant to the Alimera amended agreement prior to December 31, 2009 will also be recognized ratably over the performance period, with that portion of the consideration represented by the period from the amendment effective date to the date of receipt being recognized as revenue immediately.

Neither the fiscal 2009 nor fiscal 2008 third quarter reflected royalty income from sales of Retisert. Pursuant to a June 2005 advance royalty agreement, Bausch & Lomb has retained Retisert royalties otherwise payable to the Company and is entitled to continue to retain 100% of the next \$1.6 million of Retisert royalties otherwise payable to the Company. Accordingly, we currently do not expect to record any Retisert royalty income from Bausch & Lomb through at least the quarter ending December 31, 2009.

Royalties retained by Bausch & Lomb pursuant to the advance royalty agreement that would otherwise have been payable to the Company for the three months ended March 31, 2009 were \$288,000. This was a 22% decrease from \$371,000 otherwise payable to the Company in the same quarter a year earlier and a 37% decrease from \$458,000 otherwise payable to the Company in the immediately preceding quarter.

### **Research and Development**

Research and development decreased by approximately 1.7 million, or 48%, to approximately \$1.9 million for the three months ended March 31, 2009 from approximately \$3.6 million for the three months ended March 31, 2008. This decrease was primarily attributable to (i) the absence of \$1.2 million of Iluvien co-development costs incurred in the prior year period as a result of the assumption by Alimera of all financial responsibility for the development of licensed products under the amended collaboration agreement and (ii) a decrease of approximately \$651,000 of UK-based research and development costs, of which approximately \$380,000 was attributable to the relative strengthening of the dollar to the Pound Sterling currency and approximately \$270,000 was primarily attributable to reductions of clinical trial, legal and facilities costs. As a result of the amended Alimera agreement, the Company does not expect to incur future costs for the development of Iluvien. On a constant currency basis, we currently expect research and development expense for the fourth quarter of fiscal 2009 to change by less than 10% compared to the current quarterly period.

#### General and Administrative

General and administrative decreased by approximately \$1.5 million, or 42%, to approximately \$2.1 million for the three months ended March 31, 2009 from approximately \$3.5 million for the three months ended March 31, 2008. This decrease was primarily attributable to reduced legal, audit and related consulting fees of approximately \$1.9 million, primarily due to savings resulting from the Company's reincorporation in the U.S. in June 2008 and the absence of prior year legal fees incurred in connection with collaboration transactions, partially offset by approximately \$380,000 of severance cost obligations accrued in March 2009.

#### Change in Fair Value of Derivatives

Change in fair value of derivatives represented income of \$22,000 for the three months ended March 31, 2009 compared to income of approximately \$1.2 million for the three months ended March 31, 2008.

During the years ended June 30, 2008 and 2007, the Black-Scholes value of detachable warrants issued in share offerings denominated in Australian dollars (A\$) was recorded as a derivative liability, subject to revaluation at subsequent reporting dates. The change in fair value of derivatives for the three months ended March 31, 2009 was attributable to reductions in the remaining exercise period of the warrants, partially offset by the effect of an increase in the market price of our common shares. The change in fair value of derivatives for the three months ended March 31, 2008 was primarily attributable to a decrease in the market price of our common shares during the period. The derivative liability balance of \$352,000 at March 31, 2009 will be subject to future revaluation through the date of expiration, or earlier exercise, of the underlying warrants.

#### **Interest Income**

Interest income decreased by \$99,000, or 82%, to \$22,000 for the three months ended March 31, 2009 from \$121,000 for the three months ended March 31, 2008. This decrease was attributable to (i) a combination of lower average interest-bearing cash equivalent balances and reduced money market interest rates and (ii) the absence in this year's quarter of interest accrued in the prior year's quarter on the \$1.5 million note receivable.

## Interest Expense

Interest expense of \$206,000 was accrued for the three months ended March 31, 2008 on the portion of shared Iluvien product candidate co-development costs that we elected not to pay under the terms of the original Alimera collaboration agreement. In connection with the amended collaboration agreement with Alimera, effective March 14, 2008, the total co-development costs, including associated penalties and accrued interest, then owed by the Company to Alimera were cancelled and, accordingly, no interest expense was incurred during the three months ended March 31, 2009.

#### **Income Tax Benefit**

Income tax benefit of \$105,000 for the three months ended March 31, 2009 was predominantly due to provision adjustments associated with certain income tax return filings during the quarter. A deferred income tax benefit of \$15,000 was recorded for the three months ended March 31, 2008. For each of the three months ended March 31, 2009 and 2008, our ability to record income tax benefits associated with losses before income taxes is limited due to a valuation allowance recorded on our net deferred tax assets.

## Nine Months Ended March 31, 2009 Compared to Nine Months Ended March 31, 2008:

		ths Ended ch 31,	Chang	ge
	2009	2008	Amounts	%
		thousands except		
Revenues	\$ 8,939	<b>\$</b> 773	\$ 8,166	1,056%
Operating expenses:				
Research and development	6,177	12,022	(5,845)	(49)%
General and administrative	7,343	8,609	(1,266)	(15)%
Total operating expenses	13,520	20,631	(7,111)	(34)%
Loss from operations	(4,581)	(19,858)	15,277	(77)%
Other income (expense):				
Change in fair value of derivatives	1,578	7,193	(5,615)	(78)%
Interest income	155	534	(379)	(71)%
Interest expense		(507)	507	(100)%
Other	7	308	(301)	(98)%
Total other income	1,740	7,528	(5,788)	(77)%
Loss before income taxes	(2,841)	(12,330)	9,489	(77)%
Income tax benefit	864	239	625	262%
Net loss	\$ (1,977)	\$(12,091)	\$10,114	(84)%

## Revenues

Revenues increased by approximately \$8.2 million to \$8.9 million for the nine months ended March 31, 2009 from \$773,000 for the nine months ended March 31, 2008. The increase was attributable to revenue recognized in connection with the March 2008 amended collaboration agreement with Alimera.

There was no Retisert royalty income during the nine months ended March 31, 2009 and 2008. Royalties retained by Bausch & Lomb pursuant to the advance royalty agreement that would otherwise have been payable to the Company for the nine months ended March 31, 2009 were approximately \$1.2 million. This was a 14% decrease from approximately \$1.4 million otherwise payable to the Company for the nine months ended March 31, 2008 and a 9% decrease from approximately \$1.3 million otherwise payable to the Company for the immediately preceding nine month period ended June 30, 2008.

#### **Research and Development**

Research and development decreased by approximately \$5.8 million, or 49%, to approximately \$6.2 million for the nine months ended March 31, 2009 from approximately \$12.0 million for the nine months ended March 31, 2008. This decrease was primarily attributable to (i) the absence of \$4.7 million of Iluvien co-development costs incurred in the prior year period as a result of the assumption by Alimera of all financial responsibility for the development of licensed products under the amended collaboration agreement and (ii) a decrease of approximately \$1.1 million of UK-based research and development costs, of which approximately \$850,000 was attributable to the relative strengthening of the dollar to the Pound Sterling currency and approximately \$280,000 was primarily attributable to reductions of personnel, legal and facilities costs.

## General and Administrative

General and administrative decreased by approximately \$1.3 million, or 15%, to approximately \$7.3 million for the nine months ended March 31, 2009 from approximately \$8.6 million for the nine months ended March 31, 2008. This decrease was primarily attributable to (i) reduced legal, audit and related consulting fees of approximately \$2.7 million, primarily due to savings resulting from the Company's reincorporation in the U.S. in June 2008 and the absence of prior year legal fees incurred in connection with collaboration transactions; (ii) the absence of approximately \$450,000 of prior year period personnel and facility costs in connection with the prior year closing of the Perth, Australia office and (ii) reduced market development research for certain product candidates of \$160,000; partially offset by (i) a \$1.3 million current year provision for losses on the note receivable from GEM; (ii) increased share-based payments expense of \$300,000 attributable to current fiscal year option grants; and (iii) \$380,000 of current year severance obligations accrued in March 2009.

#### Change in Fair Value of Derivatives

Change in fair value of derivatives represented income of approximately \$1.6 million for the nine months ended March 31, 2009 compared to income of approximately \$7.2 million for the nine months ended March 31, 2008. The change in fair value of derivatives for each of the nine months ended March 31, 2009 and 2008 was primarily attributable to net decreases in the market price of our common shares during the periods and, to a lesser degree, a continuing reduction in the remaining life of the warrants.

#### **Interest Income**

Interest income decreased by \$379,000, or 71%, to \$155,000 for the nine months ended March 31, 2009 from \$534,000 for the nine months ended March 31, 2008. This decrease was attributable to (i) a combination of lower average interest-bearing cash equivalent balances and significant reductions in money market interest rates and (ii) the absence in the current year period of interest accrued in the prior year on the \$1.5 million note receivable.

#### Interest Expense

Interest expense of \$507,000 was accrued for the nine months ended March 31, 2008 on the portion of shared Iluvien product candidate co-development costs that we elected not to pay under the original Alimera collaboration agreement. In connection with the amended collaboration agreement with Alimera, effective March 14, 2008, the total co-development costs, including associated penalties and accrued interest, then owed by the Company to Alimera were cancelled and, accordingly, no interest expense was incurred during the nine months ended March 31, 2009.

#### Income Tax Benefit

Income tax benefit of \$864,000 for the nine months ended March 31, 2009 was predominantly due to the recognition of \$773,000 of foreign research and development tax credits earned by our U.K. subsidiary, which included approximately \$660,000 related to prior years. Deferred income tax benefits of \$63,000 and \$239,000 were recorded for the nine months ended March 31, 2009 and 2008, respectively. The reduced deferred tax benefit in the current year period is attributable to the fact that our ability to record tax benefits associated with losses incurred is limited by the amount of deferred tax liabilities recorded.

## Liquidity and Capital Resources

We have incurred operating losses since inception and, at March 31, 2009, we had a total accumulated deficit of \$226.5 million. Our research and development and 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. 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 equity and debt securities and the proceeds from license fees and collaboration payments to fund our operations.

Cash and cash equivalents totaled approximately \$8.0 million at March 31, 2009 compared to \$15.6 million at June 30, 2008. We believe we can fund our operations as currently conducted through at least December 31, 2010. This expectation is

based on the assumptions that we continue to receive the Pfizer quarterly \$500,000 research and development funding, Alimera continues to fund the development of Iluvien, we resume receiving Retisert royalties from Bausch & Lomb prior to June 30, 2010 and we continue to receive the scheduled conditional note payments from Alimera. However, whether and when we will require or desire to raise additional capital will depend upon many other factors, including, but not limited to:

- the continuation of our collaborations with Pfizer and Alimera on their existing terms, including the continued funding by Pfizer and Alimera of our
  programs and our receipt of applicable milestone, royalty, note and other payments, and the ability of Pfizer and Alimera to finance such funding and
  payments;
- the development, regulatory approval and commercialization of Iluvien, which is our primary product candidate currently in development;
- the amount and timing of sales of Retisert, which affect the timing of the 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 (including any Phase III clinical trials for BrachySil for pancreatic cancer), any new product candidates, or any new business opportunities;
- our ability to establish and maintain strategic arrangements for Brachysil or any other product candidates 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; and
- changes in our operating plan, including the pursuit of new business opportunities, which may affect our need for capital.

Our future cash position beyond December 31, 2010 depends significantly on the regulatory approval and marketing of Iluvien. Alimera has agreed to pay us \$25.0 million upon FDA approval of Iluvien and a 20% share in the future profits of Iluvien. There is no assurance that the FDA will approve Iluvien or that Iluvien will achieve market acceptance even if it is approved by the FDA.

The downturn in the economy and the disruptions in the financial and credit markets have made it significantly more difficult and more expensive to obtain financing. If we determine that it is desirable or necessary to raise 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 potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of 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, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

Our consolidated statements of cash flows for the nine months ended March 31, 2009 and 2008 are summarized as follows:

	2009	2008 (In thousands)	Change
Net loss:	\$(1,977)	\$(12,091)	\$ 10,114
Changes in operating assets and liabilities	(8,203)	12,919	(21,122)
Other adjustments to reconcile net loss to cash flows from operating activities	2,884	(3,531)	6,415
Net cash used in operating activities	\$(7,296)	\$ (2,703)	\$ (4,593)
Net cash used in investing activities	\$ (174)	\$ (133)	\$ (41)
Net cash provided by financing activities	\$	\$ 18,387	\$(18,387)

Net cash used in operating activities increased \$4.6 million to approximately \$7.3 million for the nine months ended March 31, 2009 compared to approximately \$2.7 million for the nine months ended March 31, 2008. The largest contributing factor was the impact of the March 2008 amended Alimera agreement. It accounted for an increase of approximately \$6.6 million of cash used in operating activities, which consisted of the absence in the current year period of \$12.0 million of upfront cash consideration received in March 2008, partially offset by the absence of approximately \$3.9 million of Iluvien co-development costs paid to Alimera in the prior year period under the terms of the original collaboration agreement and the receipt in the current year period of approximately \$1.5 million of conditional note interest and development cost reimbursements. The net decrease of approximately \$2.0 million in other operating cash activities consisted primarily of (i) a reduction of approximately \$1.5 million of legal and audit fee payments, primarily the result of the reincorporation to the U.S.; (ii) an increase of \$730,000 in collaboration agreement funding from Pfizer and Intrinsiq; (iii) a decrease of approximately \$400,000 of UK research and development tax credits in the current year period, which were partially offset by (a) an approximate \$1.0 million increase in payments of legal fees and other direct costs related to the consummation of the June 2008 reincorporation transaction and (b) \$600,000 of fiscal year 2008 bonuses paid in the current year period.

Net cash used in investing activities increased by \$41,000 and consisted entirely of purchases of property and equipment. Net cash flows provided by financing activities of \$18.4 million for the nine months ended March 31, 2008 resulted from the July 2007 issuance of 4,114,199 units at \$5.00 per unit net of issue costs. Each unit consisted of one common share and one warrant to purchase 0.4 common share, with a warrant exercise price of \$6.60 per share. Of the total, 1,300,000 units were purchased by Pfizer in accordance with the terms of the Collaborative Research and License Agreement dated April 3, 2007.

We had no borrowings or line of credit facilities as of March 31, 2009.

#### **Recently Adopted Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("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, for purposes such as derivative valuation and impairment analysis, and expands disclosures about fair value measurements. Under the standard, fair value measurements are to be separately disclosed by level within a fair value hierarchy. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements. Pursuant to FASB Staff Position ("FSP") No. 157-2, issued in February 2008, the application of SFAS 157 for nonfinancial assets and nonfinancial liabilities that are recognized or disclosed at fair value in financial statements on a non-recurring basis may be deferred until fiscal years beginning after November 15, 2008. We adopted SFAS 157 as of July 1, 2008, with the exception of the application of the statement to non-recurring nonfinancial assets and nonfinancial liabilities. See Note 11 to our condensed consolidated financial statements for additional details.

In July 2008, we adopted SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities* — *Including an Amendment of FASB Statement No. 115*" ("SFAS 159"). SFAS 159 permits companies to choose to measure selected financial assets and liabilities at fair value, with changes in fair value recognized in earnings each reporting period. Prior to July 2008, we recorded derivative liabilities at fair value in accordance with SFAS No. 133, "*Accounting for Derivative Instruments and Hedging Activities*", as amended. The adoption of SFAS 159 had no impact on our consolidated financial position and results of operations as we did not elect the fair value option for any other financial assets and liabilities.

In June 2007, the FASB issued Emerging Issues Task Force ("EITF") Issue No. EITF 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-03"), which requires nonrefundable advance payments for future research and development activities to be capitalized and recognized as an expense as the goods are delivered or the related services are performed. We adopted EITF 07-03 as of July 1, 2008 and the adoption did not have any impact on our consolidated financial statements.

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"). SFAS 161 amends and expands the disclosure requirements for derivative instruments and hedging activities, with the intent to provide users of financial statements with an enhanced understanding of (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under FASB Statement No. 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity's financial statements. We adopted SFAS 161 as of January 1, 2009. See Notes 2, 6 and 11 to our condensed consolidated financial statements for disclosures about our derivative liabilities.

#### **Recently Issued Accounting Pronouncements**

In November 2007, the FASB issued EITF Issue No. 07-01, "Accounting for Collaborative Arrangements" ("EITF 07-01"). EITF 07-01 defines a collaborative arrangement as a contractual arrangement in which the parties are (i) active participants to the arrangement; and (ii) exposed to significant risks and rewards that depend upon the commercial success of the endeavor. It also addresses the appropriate statement of operations presentation for activities and payments between the participants in a collaborative arrangement as well as for costs incurred and revenue generated from transactions with third parties. EITF 07-01 will be effective for our fiscal year beginning July 1, 2009. We are currently evaluating the potential impact of adopting EITF 07-01 on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised), "*Business Combinations*" ("SFAS 141R"), which provides revised guidance for recognition and measurement of identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree at fair value. SFAS 141R 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 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is required to be applied 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. We will be required to adopt SFAS 141R in connection with business combination transactions, if any, after June 30, 2009.

In April 2008, the FASB issued FSP No. 142-3, "*Determination of the Useful Life of Intangible Assets*" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "*Goodwill and Intangible Assets*" ("SFAS 142"). The objective of FSP 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R and other accounting principles. FSP 142-3 applies to all intangible assets, whether acquired in a business combination or otherwise, and early adoption is prohibited. We will be required to adopt FSP 142-3 for our fiscal year beginning July 1, 2009. We are currently evaluating the potential impact of adopting FSP 142-3 on our consolidated financial statements.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

### **Derivative Liabilities**

The change in fair value of derivative liabilities related to warrants denominated in A\$ resulted in income of approximately \$22,000 and \$1.6 million during the three and nine months ended March 31, 2009, 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 modest quarterly decreases of the derivative liability value.

At March 31, 2009, the closing price of our common shares traded on NASDAQ was \$1.01 per share. The following table summarizes the sensitivity of our consolidated statements of operations for the three months ended March 31, 2009 to assumed increases or decreases of our share price at March 31, 2009:

	Decrea	Decrease in Share Price			Incre	ase in Shar	e Price
	-15%	-10%	-5%	Price	+5%	+10%	+15%
			(	In thousand	s)		
Change in fair value of derivatives - income (expense)	\$ 110	\$ 75	\$ 39	\$ —	\$(41)	\$(84)	\$(129)

## **Foreign Currency Exchange Rates**

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations and the Pound Sterling is the functional currency for our U.K. operations. Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling impact the net operating expenses of our U.K. operations. For the three and nine months ended March 31, 2009, the strengthening of the U.S. dollar relative to the comparable periods of the prior year resulted in a net decrease in research and development expenses of approximately \$0.4 million and \$0.8 million, respectively. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of operations exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling also impact total stockholders' equity. During the nine months ended March 31, 2009, the relative strengthening of the U.S. dollar in relation to the Pound Sterling resulted in a net decrease of \$7.6 million in stockholders' equity due to the translation of approximately £12.2 million of net assets of our U.K. operations, predominantly the BioSilicon technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at March 31, 2009 in relation to the Pound Sterling, our stockholders' equity at March 31, 2009 would have decreased or increased, respectively, by approximately \$0.9 million.

### **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

We have established disclosure controls and procedures designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to the officers who certify our financial reports and to other members of senior management and the Board of Directors.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. As disclosed in our Form 10-K for the year ended June 30, 2008, we determined that we had a material weakness in our internal control over financial reporting as of June 30, 2008 because we failed to maintain effective controls over the accounting for complex transactions, primarily involving the application of foreign currency translation in accordance with U.S. GAAP. As discussed below, our management is in the process of actively addressing and remediating this material weakness. Our principal executive officer and principal financial officer concluded that our disclosure controls and procedures related to the application of foreign currency translation were not effective as of March 31, 2009 as a result of our unremediated material weakness.

In connection with our management's assessment of our internal control over financial reporting as reported in our annual report on Form 10-K for the year ended June 30, 2008, the following material weakness was identified as of June 30, 2008:

Subsequent to March 31, 2008, an error was identified requiring an adjustment to both Goodwill and Additional paid-in capital at March 31, 2008, December 31, 2007, September 30, 2007 and June 30, 2007 of approximately \$4.7 million. The error was the result of incorrectly translating the A\$ value of shares issued as purchase consideration for the December 2005 acquisition of CDS to \$ by using the exchange rate at the measurement date determined under A-IFRS instead of under U.S. GAAP. This error had not been identified previously because prior to June 30, 2007, as a foreign private issuer, the Company's historical financial statements, including footnote reconciliations from A-IFRS to U.S. GAAP, had been presented exclusively in A\$. Management has determined that these restatements resulted from the control deficiency that there were inadequate controls over the application of foreign currency translation under U.S. GAAP and this control deficiency constitutes a material weakness.

### Changes in internal control over financial reporting

Our management, with the participation of our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements.



During the nine months ended March 31, 2009, we have undertaken actions to remediate the material weakness identified above. These actions have included the evaluation and improvement of the design of our financial close and reporting processes and controls (including the application of foreign currency translation to routine and non-routine transactions), which has led to the implementation of new and improved processes, where warranted. These remedial measures have already been implemented and we plan to continue making assessments of and implementing such other actions, if any, that are determined to be necessary or advisable in further remediation of this area of our internal control over financial reporting.

We believe that the steps outlined above will strengthen our internal control over financial reporting and address the material weakness described above. As part of our 2009 assessment of internal control over financial reporting, our management will test and evaluate these additional controls to assess whether they are operating effectively.

#### PART II: OTHER INFORMATION

#### Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in Part I, "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended June 30, 2008.

## Item 6. Exhibits

- 10.1 Resignation letter of Michael J. Soja, Vice President, Finance and Chief Financial Officer, dated March 11, 2009
- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) and 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) and 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

# 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.

Date: May 13, 2009

# pSivida Corp.

By: /s/ Paul Ashton

Name: Paul Ashton Title: President and Chief Executive Officer

## March 11, 2009

Dr. Paul Ashton President and CEO pSivida Corp. 400 Pleasant Street Watertown, MA 02472

## Re: Resignation

## Dear Paul:

By this letter (this "Resignation Letter") I hereby resign as Vice President, Finance and Chief Financial Officer of pSivida Corp. (the "Company"), effective as of the close of business on March 20, 2009 (the "Resignation Effective Time"). I also hereby resign, effective as of the Resignation Effective Time, from all offices and other positions, including as a member of fiduciary and other committees, with the Company, the Company's subsidiaries and the Company's benefit plans. Subject to the terms and conditions of this Resignation Letter and provided that I have delivered to the Company a release of claims in the form hereto attached as <u>Exhibit A (the "Release") within 21 days following the Resignation Effective Time and do not revoke the Release within the seven-day period specified in the Release, the Company hereby agrees to provide me the benefits and payments described in Section 8(c) of my employment agreement with the Company dated as of May 16, 2006 (my "Employment Agreement"), as amended by this Resignation Letter, as though my employment had been terminated by the Company without Cause or by me for Good Cause, following adequate prior notice, as of the Resignation Effective Time. This Resignation Letter amends my Employment Agreement as follows:</u>

- (1) The requirements under my Employment Agreement for notice prior to termination of employment will be deemed satisfied by this Resignation Letter.
- (2) The Company will not make any payments described under Section 8(c)(i) of my Employment Agreement. Instead, the Company will pay me a total of \$413,149.00 in cash in the following manner: (a) within 2 business days of the effective date of the Release, a lump sum payment of \$37,559, and (b) a lump sum payment of \$37,559 on each of April 30, 2009, May 31, 2009, June 30, 2009, July 31, 2009, August 31, 2009, September 30, 2009, October 31, 2009, November 30, 2009, December 31, 2009 and January 31, 2010.
- (3) Notwithstanding the terms of any agreement to the contrary, including without limitation the terms of the Non-statutory Stock Option certificate evidencing the stock option granted to me on September 4, 2008 over 100,000 shares of common stock (the "September 4<sup>th</sup> Option Grant") and the Non-statutory Stock Option certificate evidencing the stock option granted to me on September 10, 2008 over 10,000 shares of common stock (the "September 10, 2008 Option Grant"), the September 4<sup>th</sup> Option Grant and the September 10<sup>th</sup> Option Grant will be deemed to have automatically and immediately vested and become exercisable upon the termination of my employment and, provided the Release becomes effective as provided above, remain exercisable for a period of one (1) year following the Resignation Effective Time. If the Release does not become effective as provided above, the September 4<sup>th</sup> Option Grant and the September 10<sup>th</sup> Option Grant will cease to be exercisable on the 28th day following the Resignation Effective Time.

Except as provided in this Resignation Letter, the terms of my Employment Agreement shall continue in full force and effect to the extent provided in my Employment Agreement.

I also agree that I will not disparage the Company or any of its employees, officers, directors or agents in communications with third parties.

I understand that all payments made to me shall be subject to applicable tax withholding and that the Company will not be liable for any additional taxes, or any penalties or interest, with respect to any amounts that may be payable to me.

If the Company agrees to these terms, please so indicate by executing this letter agreement in the space indicated below, whereupon my resignation will take effect on the terms indicated above.

/s/ Michael J. Soja

Michael J. Soja

The Company agrees to the terms hereinabove specified, effective as of the date of this letter agreement.

/s/ Lori Freedman

By: Lori Freedman

Title: Vice President, Corporate Affairs, General Counsel and Secretary

## EXHIBIT A

## RELEASE OF CLAIMS

FOR AND IN CONSIDERATION OF the benefits to be provided me in connection with the termination of my employment, as set forth in the employment agreement between me and pSivida Corp. (the "Company") dated as of May 16, 2006, as amended by my Resignation Letter dated March 11, 2009 (the "Agreement"), which benefits are subject to my signing of this Release of Claims and to which I am not otherwise entitled, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I, on my own behalf and on behalf of my heirs, executors, administrators, beneficiaries, representatives and assigns, and all others connected with me, hereby release and forever discharge the Company, its subsidiaries and other affiliates and all of their respective past, present and future officers, directors, trustees, shareholders, employees, agents, general and limited partners, members, managers, joint venturers, representatives, successors and assigns, and all others connected with any of them, both individually and in their official capacities, from any and all causes of action, rights and claims of any type or description, known or unknown, which I have had in the past, now have, or might now have, through the date of my signing of this Release of Claims, in any way resulting from, arising out of or connected with my employment by the Company or any of its subsidiaries or other affiliates or the termination of that employment or pursuant to any federal, state or local law, regulation or other requirement (including without limitation Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Americans with Disabilities Act, and the fair employment practices laws of the state or states in which I have been employed by the Company or any of the subsidiaries or other affiliates, each as amended from time to time).

Excluded from the scope of this Release of Claims is (i) any claim arising under the terms of the Agreement and (ii) any right of indemnification or contribution that I have pursuant to the Certificate of Incorporation, Constitution, By-Laws or other governing documents of the Company or any of its subsidiaries or other affiliates.

In signing this Release of Claims, I acknowledge my understanding that I may not sign it prior to the termination of my employment, but that I may consider the terms of this Release of Claims for up to twenty-one (21) days (or such longer period as the Company may specify) from the later of the date my employment with the Company terminates or the date I receive this Release of Claims. I also acknowledge that I am advised by the Company and its affiliates to seek the advice of an attorney prior to signing this Release of Claims; that I have had sufficient time to consider this Release of Claims and to consult with an attorney, if I wished to do so, or to consult with any other person of my choosing before signing; and that I am signing this Release of Claims voluntarily and with a full understanding of its terms.

I further acknowledge that, in signing this Release of Claims, I have not relied on any promises or representations, express or implied, that are not set forth expressly in the Agreement. I understand that I may revoke this Release of Claims at any time within seven (7) days of the date of my signing by written notice to the General Counsel of the Company and that this Release of Claims will take effect only upon the expiration of such seven-day revocation period and only if I have not timely revoked it.

Intending to be legally bound, I have signed this Release of Claims under seal as of the date written below.

Signature: /s/ Michael J. Soja

Name (please print): Michael J. Soja

Date Signed: March 21, 2009

## 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 CORP**.;
- 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 13, 2009

# /s/ Paul Ashton

Name: Paul Ashton Title: President and Chief Executive Officer (Principal Executive Officer)

## 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, **Leonard S. Ross**, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of **PSIVIDA CORP**.;
- 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 13, 2009

/s/ Leonard S. Ross

Name: Leonard S. Ross Title: Corporate Controller (Principal 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 Corp. (the "Company") on Form 10-Q for the quarter ended March 31, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Ashton, President and Chief Executive 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 13, 2009

/s/ Paul Ashton

Name: Paul Ashton Title: President and Chief Executive Officer (Principal Executive Officer)

## 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 Corp. (the "Company") on Form 10-Q for the quarter ended March 31, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard S. Ross, Corporate Controller 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 13, 2009

/s/ Leonard S. Ross

Name: Leonard S. Ross Title: Corporate Controller (Principal Financial Officer)