# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# **FORM 10-Q**

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

For the quarterly period ended September 30, 2012

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**COMMISSION FILE NUMBER 000-51122** 



(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

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  $\square$ 

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 🗵 No 🗆

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		Accelerated filer	
Non-accelerated filer	□ (Do not check if a smaller reporting company)	Smaller reporting company	$\times$
Indicate by check m	ark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).	Yes 🗆 No 🗵	

There were 23,297,011 shares of the registrant's common stock, \$0.001 par value, outstanding as of November 7, 2012.

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

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# PART I. FINANCIAL INFORMATION

# Item 1. Unaudited Financial Statements

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

	Sep	otember 30, 2012		June 30, 2012
Assets				
Current assets:				
Cash and cash equivalents	\$	8,388	\$	4,625
Marketable securities		9,258		9,946
Accounts and other receivables		938		967
Prepaid expenses and other current assets		316		421
Total current assets		18,900		15,959
Property and equipment, net		289		335
Intangible assets, net		4,078		4,226
Other assets		72		77
Total assets	\$	23,339	\$	20,597
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	266	\$	394
Accrued expenses		801		608
Deferred revenue		2,395		2,176
Total current liabilities		3,462		3,178
Deferred revenue		3,714		3,783
Total liabilities		7,176	_	6,961
Stockholders' equity:				
Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding				
Common stock, \$.001 par value, 60,000,000 shares authorized, 23,297,011 and 20,802,592 shares issued and				
outstanding at September 30, 2012 and June 30, 2012, respectively		23		21
Additional paid-in capital		269,440		264,431
Accumulated deficit		(254,309)	(	251,758)
Accumulated other comprehensive income		1,009	_	942
Total stockholders' equity		16,163		13,636
Total liabilities and stockholders' equity	\$	23,339	\$	20,597

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See notes to condensed consolidated financial statements

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

		nths Ended nber 30,
	2012	2011
Revenues:		
Collaborative research and development	\$ 169	\$ 1,461
Royalty income	384	198
Total revenues	553	1,659
Operating expenses:		
Research and development	1,523	2,129
General and administrative	1,620	2,061
Total operating expenses	3,143	4,190
Loss from operations	(2,590)	(2,531)
Other income (expense):		
Change in fair value of derivatives	_	42
Interest income	7	9
Other expense, net	(1)	(2)
Total other income	6	49
Loss before income taxes	(2,584)	(2,482)
Income tax benefit	33	55
Net loss	\$ (2,551)	\$ (2,427)
Net loss per common share - basic and diluted	\$ (0.11)	\$ (0.12)
Weighted average common shares - basic and diluted	22,294	20,757
Net loss	\$ (2,551)	\$ (2,427)
Other comprehensive income (loss):		
Foreign currency translation adjustments	59	(363)
Net unrealized gain (loss) on marketable securities	8	(2)
Other comprehensive income (loss)	67	(365)
Comprehensive loss	\$ (2,484)	\$ (2,792)

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See notes to condensed consolidated financial statements

# PSIVIDA CORP. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) (In thousands, except share amounts)

	Common Number of Shares	Par	Value ount	Additional Paid-In Capital	Accumulated Deficit	( Comp	umulated Other prehensive ncome	Total ckholders' Equity
Balance at July 1, 2012	20,802,592	\$	21	\$264,431	\$ (251,758)	\$	942	\$ 13,636
Net loss			—		(2,551)		—	(2,551)
Other comprehensive income			_				67	67
Issuance of stock, net of issue costs	2,494,419		2	4,666			—	4,668
Stock-based compensation	—		—	343	_			343
Balance at September 30, 2012	23,297,011	\$	23	\$269,440	\$ (254,309)	\$	1,009	\$ 16,163

See notes to condensed consolidated financial statements

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

		nths Ended nber 30,
	2012	2011
Cash flows from operating activities:		<i></i>
Net loss	\$(2,551)	\$ (2,427)
Adjustments to reconcile net loss to cash flows from operating activities:		
Amortization of intangible assets	193	833
Depreciation of property and equipment	55	24
Change in fair value of derivatives	_	(42)
Stock-based compensation expense	343	477
Amortization of bond premium on marketable securities	44	85
Deferred tax benefit	—	(13)
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	147	206
Accounts payable and accrued expenses	(2)	(373)
Deferred revenue	150	(1,430)
Net cash used in operating activities	(1,621)	(2,660)
Cash flows from investing activities:		
Purchases of marketable securities	(2,799)	(3,731)
Maturities of marketable securities	3,450	3,400
Purchases of property and equipment	(4)	(221)
Net cash provided by (used in) investing activities	647	(552)
Cash flows from financing activities:		
Proceeds from issuance of stock, net of issuance costs	4,735	
Exercise of stock options		114
Net cash provided by financing activities	4,735	114
Effect of foreign exchange rate changes on cash and cash equivalents	2	(3)
Net increase (decrease) in cash and cash equivalents	3,763	(3,101)
Cash and cash equivalents at beginning of period	4,625	12,912
Cash and cash equivalents at end of period	\$ 8,388	\$ 9,811
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment	\$ —	\$ 88
Stock issuance costs	67	_
See notes to condensed consolidated financial statements		

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") as of September 30, 2012 and for the three months ended September 30, 2012 and 2011 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, 2012. 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, 2012, and include all adjustments that are necessary for the fair presentation of the Company's financial position, results of operations, comprehensive loss and cash flows for the periods indicated. The preparation of financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") 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 months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the entire fiscal year or any future period.

The Company develops tiny, sustained release, drug delivery products designed to deliver drug at a controlled and steady rate for months or years. The Company is focused on the treatment of chronic eye diseases utilizing its core technology systems, Durasert<sup>™</sup> and BioSilicon<sup>™</sup>. The Company currently has three approved products and two principal product candidates under development, which represent successive generations of the Durasert technology platform.

The Company's most recently approved product is an injectable, sustained-release micro-insert for the treatment of vision impairment associated with chronic diabetic macular edema ("DME") considered insufficiently responsive to available therapies. This product has received marketing authorization in the United Kingdom ("U.K."), Austria, France, Germany and Portugal, and has been recommended for approval in Italy and Spain. The product is being developed by the Company's licensee, Alimera Sciences, Inc. ("Alimera"), and will be marketed under the name ILUVIEN<sup>®</sup>. Alimera has announced its intention to proceed with the direct commercial launch of ILUVIEN in three European countries in 2013, with Germany expected in the first quarter, the U.K. in the second quarter and France in the third quarter, and has completed a \$40.0 million equity financing to provide additional capital to launch ILUVIEN in those three countries. Alimera also indicated its intention to resubmit its New Drug Application ("NDA") for ILUVIEN for DME to the U.S. Food and Drug Administration ("FDA") during the first quarter of 2013, following receipt of a November 2011 Complete Response Letter ("2011 CRL"). Based on a June 2012 meeting with the FDA, Alimera reported that it intends to use data from its two previously completed pivotal Phase III clinical trials (the "FAME<sup>TM</sup> Study") and to focus on the population of patients with chronic DME considered insufficiently responsive to available therapies, the same group for which regulatory approval was granted in various EU countries.

The Company plans to study the same micro-insert used in ILUVIEN for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye ("posterior uveitis"). The FDA has cleared the Company's Investigational New Drug ("IND") application, permitting it to move directly to two Phase III clinical trials for this indication, involving a total of approximately 300 patients, without the necessity of conducting Phase I or Phase II trials.

The Company is developing a bioerodible, injectable micro-insert delivering latanoprost (the "Latanoprost Product") to treat glaucoma and ocular hypertension. An investigator-sponsored Phase I/II dose-escalation study is ongoing to assess the safety and efficacy of this micro-insert in patients with elevated intraocular pressure. The Company granted Pfizer Inc. ("Pfizer") an exclusive option, under various circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

The Company's two FDA-approved products, Retisert<sup>®</sup> for the treatment of posterior uveitis and Vitrasert<sup>®</sup> for the treatment of AIDS-related cytomegalovirus retinitis, are surgically implanted. They are both licensed to Bausch & Lomb Incorporated ("Bausch & Lomb").

BioSilicon, the Company's second key technology platform targeted for sustained drug delivery, utilizes fully-erodible, nanostructured, porous material. The Company's primary focus is on Tethadur<sup>TM</sup>, which utilizes BioSilicon to deliver large biologic molecules, including peptides and proteins, on a sustained basis. The sizes of the pores in the BioSilicon material are manufactured using nanotechnology to accommodate specific protein, peptide or antibody molecules. These molecules are then released and the material erodes slowly over time. The BioSilicon technology can also be designed to deliver smaller molecules.

The Company is subject to risks, including, but not limited to, the ability of Alimera to successfully complete pricing and reimbursement discussions and to successfully finance and execute the direct commercialization of, and achieve market acceptance of, ILUVIEN for DME in the applicable EU countries; the ability of Alimera to achieve FDA approval of ILUVIEN for DME following its planned NDA resubmission, and if so, to successfully commercialize, and achieve market acceptance of, the product in the U.S.; the Company's ability, and that of its collaboration partners, to obtain adequate financing to fund its and their respective operations through collaborations, sales of securities or otherwise, to successfully advance research, pre-clinical and clinical development of, and obtain regulatory approvals for, product candidates utilizing the Company's technologies and to successfully commercialize them, to protect proprietary technologies, to comply with FDA and other governmental regulations and approval requirements and to execute on business strategies; competitive products and new disease treatments; and dependence on key personnel.

The Company has a history of operating losses and has financed its operations in recent years primarily from license fees, research and development funding and contingent cash payments from its collaboration partners, and from sales of equity securities. The Company believes that its cash, cash equivalents and marketable securities of \$17.6 million at September 30, 2012 should enable the Company to maintain its current and planned operations through calendar year 2013, including plans for Phase III clinical trials of the posterior uveitis micro-insert. The Company's funding of its operations beyond 2013 will depend on the amount and timing of cash receipts pursuant to its existing collaboration agreements with Alimera, Pfizer and Bausch & Lomb and any potential future collaborations, as well as any possible future financing transactions.

References to "\$" are to U.S. dollars and references to "A\$" are to Australian dollars.

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective dates. Unless otherwise disclosed below, the Company believes that the impact of recently issued pronouncements will not have a material impact on the Company's financial position, results of operations and cash flows or do not apply to the Company's operations.

In June 2011, the FASB issued ASU 2011-5 *Comprehensive Income (Topic 220) – Presentation of Comprehensive Income*, which provides new guidance on the presentation of comprehensive income. This guidance requires a company to present components of net income (loss) and other comprehensive income in one continuous statement or in two separate, but consecutive, statements. There are no changes to the components that are recognized in net income (loss) or other comprehensive income under current GAAP. The Company adopted this standard for the quarter ended September 30, 2012 and has presented the required information in one continuous statement of operations and comprehensive loss on a comparative basis. Other than a change in presentation, the adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

#### 2. License and Collaboration Agreements

#### Alimera Sciences, Inc.

In February 2005, the Company granted Alimera an exclusive worldwide license to manufacture, develop, market and sell ILUVIEN for the treatment and prevention of eye diseases in humans other than uveitis. Under the collaboration agreement, the Company and Alimera agreed to collaborate on the development of ILUVIEN for DME and to share the development expenses equally.

In connection with a March 2008 amendment (as amended, the "Alimera Agreement"), the Company received \$12.0 million in cash and a \$15.0 million conditional, interest-bearing note, Alimera cancelled \$5.7 million of accrued development cost liabilities then owed by the Company, Alimera agreed that it would pay a \$25.0 million milestone payment upon FDA approval of ILUVIEN for DME and would assume all financial responsibility for the development of licensed products under the Alimera Agreement, which had previously been shared equally. In exchange, the Company decreased its share in any future net profits, as defined, on sales of ILUVIEN by Alimera from 50% to 20%, measured quarterly on a country-by-country basis, subject to an offset of 20% of pre-profitability net losses, as defined, previously incurred by Alimera on a country-by-country basis. In the event that Alimera sublicenses commercialization, the Company is entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions.

The Company considered the Alimera Agreement to be a revenue arrangement with multiple deliverables and, having determined that its deliverables did not have stand-alone value, concluded that the deliverables represented a single unit of accounting. The terms of the Alimera Agreement defined the end period of the Company's performance obligations as December 31, 2009 and, accordingly, the total initial consideration of \$18.3 million was deferred and recognized as revenue on a straight-line basis over the 21.5 month performance period ended December 31, 2009. Additional cash consideration received from Alimera during the performance period, which consisted of conditional note interest payments and development cost reimbursements, was recognized as revenue during the performance period using the cumulative catch-up method. As a conditional payment obligation, the \$15.0 million Alimera note was not recorded as an asset but instead treated as contingent future revenue consideration. Amounts received from Alimera subsequent to December 31, 2009, including payment in full of the conditional note in April 2010, were, and any future milestone and profit share payments will be, recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amount is both fixed and determinable and reasonably assured of collectibility.

Revenue related to the Alimera Agreement totaled \$19,000 and \$31,000 for the three months ended September 30, 2012 and 2011, respectively.

#### Pfizer

In April 2007, the Company entered into a worldwide Collaborative Research and License Agreement with Pfizer (the "Original Pfizer Agreement") for the use of certain of the Company's technologies in ophthalmic applications that were not licensed to others. Commencing in 2008, Pfizer paid the Company \$500,000 quarterly in consideration of the Company's costs in performing research under the agreement.

In June 2011, the Company and Pfizer entered into an Amended and Restated Collaborative Research and License Agreement (the "Restated Pfizer Agreement") to focus solely on the development of the Latanoprost Product, a sustained-release bioerodible micro-insert designed to deliver latanoprost for human ophthalmic disease or conditions other than uveitis. The Original Pfizer Agreement was effectively terminated, including the cessation of Pfizer's \$500,000 quarterly research funding. Pfizer made an upfront payment of \$2.3 million and the Company assumed Pfizer's agreement with respect to an investigator-sponsored Phase I/II dose-escalation study to assess the safety and efficacy of this insert for patients with ocular hypertension and glaucoma. The Company agreed to use commercially reasonable efforts to fund development of the Latanoprost Product, with technical assistance from Pfizer, for at least one year and, thereafter, at the Company's option, through completion of Phase II clinical trials, designated as Proof-of-Concept ("POC"). Within 90 days following receipt of the Company's final report demonstrating POC, Pfizer may exercise its option for an exclusive, worldwide license to develop and commercialize the Latanoprost Product in return for a \$20.0 million payment, double-digit sales-based royalties and additional development, regulatory and sales performance milestone payments of up to \$146.5 million. If the Company elects to cease development of the Latanoprost Product after one year, but prior to completion of Phase II clinical trials, Pfizer would then have the right to exercise an option for an exclusive worldwide license to develop and commercialize the Latanoprost Product upon payment of a lesser option fee, with comparable reductions in future sales-based royalties and other designated milestones. If Pfizer does not exercise its option, the Restated Pfizer Agreement will automatically terminate, provided, however, that the Company will retain the right to develop and commercialize the Latanoprost P

Based upon the significant changes to the terms of the Original Pfizer Agreement, which included (i) changes in the consideration payable by Pfizer; (ii) changes in the deliverables; and (iii) changes in the research program, which now is solely related to the Latanoprost Product, the Company considered the Restated Pfizer Agreement a material modification and applied the applicable accounting guidance to this arrangement.

The Company's deliverables under the Restated Pfizer Agreement include conducting the research and development program for the Latanoprost Product through completion of Phase II clinical trials (the "R&D program") and participation on a Joint Steering Committee ("JSC"). Having determined that the JSC does not have standalone value from the R&D program, the Company combined these deliverables into a single unit of accounting. The performance period is the expected period over which the services of the combined unit are performed, which the Company currently expects will extend through approximately June 2015.

The total arrangement consideration of the Restated Pfizer Agreement totaled \$10.05 million, which consisted of \$7.75 million of deferred revenue on the Company's balance sheet at the effective date plus the \$2.3 million upfront payment. The difference between the total arrangement consideration and the estimated selling price of the combined deliverables, or \$3.3 million, was recognized as collaborative research and development revenue in the quarter ended June 30, 2011, the period of the modification. To determine the estimated selling price, the Company applied an estimated margin to its cost projections for the combined deliverable. The estimated selling price of \$6.7 million is being recognized as collaborative research and development revenue over the expected performance period of approximately 4 years using the proportional performance method. The Company recorded revenue of \$150,000 for the three months ended September 30, 2012 and \$288,000 for the three months ended September 30, 2011. At September 30, 2012 and June 30, 2012, the Company recorded deferred revenue of \$5.8 million and \$6.0 million, respectively, classified between current and non-current deferred revenue. Costs associated with conducting the R&D program are reflected in operating expenses in the period in which they are incurred.

If any subsequent payments are received from Pfizer, including option exercise, milestone and sales-based royalty consideration, which would occur after completion of the Company's performance period under the Restated Pfizer Agreement, such payments would be recognized as revenue when all the revenue criteria are met.

#### Intrinsiq

In January 2008, the Company and Intrinsiq Materials Cayman Limited ("Intrinsiq") entered into an agreement pursuant to which Intrinsiq acquired an exclusive field-of-use license to develop and commercialize nutraceutical and food science applications of BioSilicon, and certain related assets, for \$1.2 million. Provided the license agreement remained in effect, Intrinsiq was obligated to pay the Company aggregate minimum royalties of \$3.55 million through April 2014, of which the first \$450,000 was paid in July 2009.

The Company 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 recognized collaborative research and development revenue using the cumulative catch-up method.

In July 2011, the Company consummated an asset purchase agreement, in which it acquired porous BioSilicon-related capital equipment assets of Intrinsiq for \$223,000, and employed four former Intrinsiq employees. The fair value of the tangible assets acquired approximated the total acquisition consideration. Coincident with the transaction, Intrinsiq terminated the agreements underlying its original 2008 license. The license termination resulted in the recognition of collaborative research and development revenue of \$1.1 million in the three months ended September 30, 2011, representing the total Intrinsiq deferred revenue balance at June 30, 2011.

#### Bausch & Lomb

The Company's Retisert and Vitrasert products have been commercialized under a licensing and development agreement with Bausch & Lomb. Pursuant to the agreement as amended, Bausch & Lomb has a worldwide exclusive license to make and sell Vitrasert and the Company's first-generation products (as defined in the agreement, including Retisert) in return for royalties based on sales.

Royalty income totaled \$384,000 and \$198,000 for the three months ended September 30, 2012 and 2011, respectively. Accounts receivable from Bausch & Lomb totaled \$384,000 and \$442,000 at September 30, 2012 and June 30, 2012, respectively.

#### 3. Intangible Assets

The reconciliation of intangible assets for the three months ended September 30, 2012 and for the year ended June 30, 2012 is as follows:

	 onths Ended per 30, 2012 (In thousands)	Year Ended June 30, 2012		
Patented technologies	, , , , ,			
Gross carrying amount at beginning of period	\$ 39,556	\$	55,422	
Asset impairment write-down	_		(14,830)	
Foreign currency translation adjustments	829		(1,036)	
Gross carrying amount at end of period	 40,385		39,556	
Accumulated amortization at beginning of period	 (35,330)		(33,858)	
Amortization expense	(193)		(2,037)	
Foreign currency translation adjustments	(784)		565	
Accumulated amortization at end of period	 (36,307)	_	(35,330)	
Net book value at end of period	\$ 4,078	\$	4,226	

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization of intangible assets totaled \$193,000 and \$833,000 for the three months ended September 30, 2012 and 2011, respectively. The carrying value of intangible assets at September 30, 2012 of \$4.1 million will be amortized on a straight-line basis over the remaining estimated useful life of 5.25 years, or approximately \$780,000 per year. Of the total net book value at September 30, 2012, approximately \$2.8 million was attributable to the Durasert technology and \$1.3 million was attributable to the BioSilicon technology.

In November 2011, the FDA issued the 2011 CRL and did not grant marketing approval for ILUVIEN for DME, and, as a result, the Company did not receive a \$25.0 million milestone payment from Alimera and Alimera was unable to commence marketing ILUVIEN for DME in the U.S. Following the public announcement of the 2011 CRL, there was a significant decline in the Company's share price, resulting in a decrease of the Company's market capitalization from \$82.0 million to \$23.1 million at December 31, 2011. The combination of the 2011 CRL and the decline in the Company's share price were determined to be impairment indicators of the Company's finite-lived intangible assets, which resulted in a \$14.8 million impairment write-down for the quarter ended December 31, 2011.

## 4. Marketable Securities

The amortized cost, unrealized (loss) gain and fair value of the Company's available-for-sale marketable securities at September 30, 2012 and June 30, 2012 were as follows:

		September 30, 2012	
	Amortized Cost	Unrealized (Loss) Gain	Fair Value
		(In thousands)	
Corporate bonds	\$ 6,061	\$ (1)	\$6,060
Commercial paper	2,697	1	2,698
Certificates of deposit	500	_	500
Total marketable securities	\$ 9,258	\$	\$9,258

		June 30, 2012	
	Amortized	Unrealized	Fair
	Cost	Loss	Value
		(In thousands)	
Corporate bonds	\$ 5,958	\$ (8)	\$5,950
Commercial paper	3,046	—	3,046
Certificates of deposit	950	—	950
Total marketable securities	\$ 9,954	\$ (8)	\$9,946

During the three months ended September 30, 2012, approximately \$2.8 million of marketable securities were purchased and \$3.5 million matured. At September 30, 2012, the marketable securities had maturities ranging between zero and eight months, with a weighted average maturity of 3.2 months.

#### 5. Fair Value Measurements

The Company accounts for certain assets and liabilities at fair value. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. The Company categorizes each of its fair value measurements in one of these three levels based on the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1—Inputs are quoted prices in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2—Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transaction (less active markets).
- Level 3—Inputs are unobservable estimates 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.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At September 30, 2012 and June 30, 2012, substantially all of the Company's interest-bearing cash equivalent balances were concentrated in one institutional money market fund that has investments consisting primarily of certificates of deposit, commercial paper, time deposits, U.S. government agencies, treasury bills and treasury repurchase agreements. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

The Company's cash equivalents and marketable securities are classified within Level 1 or Level 2 on the basis of valuations using quoted market prices or alternative pricing sources and models utilizing market observable inputs, respectively. Certain of the Company's corporate debt securities were valued based on quoted prices for the specific securities in an active market and were therefore classified as Level 1. The remaining marketable securities have been valued on the basis of valuations provided by third-party pricing services, as derived from such services' pricing models. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security, and have been classified as Level 2.

The following table summarizes the Company's assets and liabilities carried at fair value measured on a recurring basis at September 30, 2012 and June 30, 2012 by valuation hierarchy:

				Septe	mber 30, 201	12		
	To	tal carrying value	acti	ted prices in ve markets Level 1)	obser	ficant other vable inputs Level 2)	unobserv	nificant vable inputs evel 3)
				(Ir	n thousands)			·
Assets:								
Cash equivalents	\$	7,187	\$	7,036	\$	151	\$	—
Marketable securities								
Corporate bonds		6,060		4,276		1,784		_
Commercial paper		2,698		_		2,698		_
Certificates of deposit		500		_		500		_
	\$	16,445	\$	11,312	\$	5,133	\$	
				Jun	e 30, 2012			
		carrying /alue	active	d prices in e markets evel 1)	observ	icant other able inputs evel 2)	unobserv	nificant vable inputs evel 3)
				(In	thousands)			,
Assets:								
Cash equivalents	\$	4,292	\$	4,042	\$	250	\$	
Marketable securities								
Corporate bonds		5,950		3,684		2,266		
Commercial paper		3,046				3,046		
Certificates of deposit		950		_		950		
	\$	14,238	\$	7,726	\$	6,512	¢	
	Ψ	14,200	ψ	7,720	Ψ	0,512	Ψ	

The Company's derivative liabilities, related to investor warrants that were denominated in Australian dollars, were historically classified as Level 3 and were valued using the Black-Scholes model. The last of these warrants expired in July 2012 and the derivative liability balance was zero at September 30, 2012 and June 30, 2012.

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

	Three Months Ended	Three Months Ended September 30,				
	2012	2	2011			
	(In thousan	ıds)				
Balance at beginning of period	\$ —	\$	170			
Change in fair value of derivative - other income			42			
Balance at end of period	<u>\$                                    </u>	\$	128			

## 6. Stockholders' Equity

In August 2012, the Company completed a registered direct offering of 2,494,419 shares of its common stock and warrants to purchase 623,605 shares of its common stock to institutional investors for gross proceeds of \$5.4 million. The shares and warrants were sold in units, each unit consisting of one share together with 0.25 of one warrant, at a negotiated price of \$2.15 per unit. Each whole warrant has an exercise price of \$2.50 per share and a five-year term, provided, however, that the warrants are not exercisable for a period of six months from date of issuance. Placement agent fees and other share issue costs totaled \$694,000.

# Warrants to Purchase Common Shares

The following table provides a reconciliation of all US\$ warrants for the three months ended September 30, 2012 and 2011:

	Three Months Ended September 30,				
	2012		2011	2011	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price	
Balance at beginning of period	2,064,710	\$ 6.17	7,614,748	\$ 7.35	
Issued	623,605	2.50			
Expired	(1,512,210)	6.60	(2,281,250)	7.50	
Balance at end of period	1,176,105	\$ 3.67	5,333,498	\$ 7.29	
Exercisable at end of period	552,500	\$ 5.00	5,333,498	\$ 7.29	

At September 30, 2012, the remaining term of outstanding US\$ warrants ranged from 3.3 to 4.9 years, representing a weighted average period of 4.1 years.

At September 30, 2011, the Company had 205,479 warrants outstanding denominated in A\$ with an exercise price of A\$7.68 (\$7.52). These warrants expired unexercised in July 2012. During the three months ended September 30, 2012 and 2011, there were no A\$-denominated warrants issued or exercised.

#### 2008 Incentive Plan

The Company's 2008 Incentive Plan (the "2008 Plan") provides for the issuance of a maximum of 4,841,255 shares of common stock in satisfaction of stock-based awards to directors, executives, employees and consultants.

The following table provides a reconciliation of stock option activity under the 2008 Plan for the three months ended September 30, 2012:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2012	3,053,355	\$ 3.10	,	
Granted	307,760	2.14		
Outstanding at September 30, 2012	3,361,115	\$ 3.01	7.43	\$ 310
Outstanding at September 30, 2012 - vested or unvested and expected to vest	3,308,868	\$ 3.00	7.42	\$ 310
Exercisable at September 30, 2012	2,119,860	\$ 2.78	6.86	\$ 275

Option grants for the three months ended September 30, 2012 consisted of 307,760 options with ratable annual vesting over 4 years and a grant date fair value of \$1.65 per share. A total of 451,826 options vested during the three months ended September 30, 2012. All option grants have a 10-year contractual life.

In determining the grant date fair value of options, the Company uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of employee options awarded during the three months ended September 30, 2012 based on the following key assumptions:

Option life (in years)	6.25
Stock volatility	95%
Risk-free interest rate	0.83%
Expected dividends	0%

#### **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. As of June 30, 2008, no further options could be granted under the Plan. Options outstanding under the Plan had vesting periods ranging from immediate vesting to 3-year graded vesting, a contractual life of five years and are denominated in A\$.

During the three months ended September 30, 2012, the last remaining 112,500 options under the Plan expired unexercised.

#### **Stock-Based Compensation Expense**

The Company's statements of operations included total compensation expense from stock-based payment awards for the three months ended September 30, 2012 and 2011, as follows:

	 Three Months Ended September 30,			
	2012		2011	
	(In thousands)			
Compensation expense included in:				
Research and development	\$ 179	\$	147	
General and administrative	164		330	
	\$ 343	\$	477	

At September 30, 2012, there was approximately \$1.3 million of unrecognized compensation expense related to unvested options under the 2008 Plan, which is expected to be recognized as expense over a weighted average period of 1.9 years.

#### 7. Income Taxes

The Company recognizes 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 its historical losses from operations, the Company established a valuation allowance for the net deferred tax assets. The Company recorded an income tax benefit of \$33,000 and \$55,000 for the three months ended September 30, 2012 and 2011, respectively. These income tax benefits primarily related to earned foreign research and development tax credits.

For the three months ended September 30, 2012 and 2011, the Company had no significant unrecognized tax benefits. At September 30, 2012 and June 30, 2012, the Company had no accrued penalties or interest related to uncertain tax positions.

# 8. 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 exercise 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 months ended September 30, 2012 and 2011 as their inclusion would be anti-dilutive.

Potentially dilutive shares at September 30, 2012 and 2011 were as follows:

	Septem	September 30,		
	2012	2011		
Options	3,361,115	2,979,876		
Warrants	1,176,105	5,538,977		
	4,537,220	8,518,853		

#### 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 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"). Such statements give our current expectations or forecasts of future events; they do not relate strictly to historical or current facts. All statements other than statements of current or historical facts are forward-looking statements, including, without limitation, any expectations of revenues, expenses, cash flows, earnings or losses from operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development and commercialization timelines; any statements of expectations or belief; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as "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 anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: uncertainties with respect to: Alimera's ability to finance, achieve additional marketing approvals, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; Alimera's resubmission of its NDA for ILUVIEN for DME and its ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the U.S.; financing and success of Phase III posterior uveitis trials, including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its option; development of products using Tethadur and BioSilicon; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution; possible influence by Pfizer; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. You should read and interpret any forward-looking statements together with these risks. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forwardlooking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the date on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

#### **Our Business**

We develop tiny, sustained-release, drug delivery products designed to deliver drug at a controlled and steady rate for months or years. We are focused on treatment of chronic eye diseases utilizing our core technology platforms, Durasert and BioSilicon. We currently have three approved products and two principal product candidates under development, which represent successive generations of our Durasert technology platform.

*ILUVIEN*. Our most recently approved product is an injectable, sustained-release micro-insert for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. This product has received marketing authorization in the U.K., Austria, France, Germany and Portugal, and has been recommended for approval in Italy and Spain. The product is being developed by our licensee, Alimera, and will be marketed under the name ILUVIEN. Alimera has announced its intention to proceed with the direct commercial launch of ILUVIEN in three European countries in 2013, with Germany expected in the first quarter, the U.K. in the second quarter and France in the third quarter, and has completed a \$40.0 million equity financing to provide additional capital to launch ILUVIEN in those three countries. Alimera also indicated its intention to resubmit its NDA for

ILUVIEN for DME to the FDA during the first quarter of 2013, following receipt of the 2011 CRL. Based on a June 2012 meeting with the FDA, Alimera reported that it intends to use data from its two previously completed pivotal Phase III clinical trials and to focus on the population of patients with chronic DME considered insufficiently responsive to available therapies, the same group for which regulatory approval was granted in various EU countries.

*Durasert Product Development*. We plan to study the same micro-insert used in ILUVIEN for the treatment of posterior uveitis. The FDA has cleared our IND, permitting us to move directly to two Phase III trials for this indication, involving a total of approximately 300 patients, without the necessity of conducting Phase I or Phase II trials.

We are developing a bioerodible, injectable micro-insert delivering latanoprost to treat glaucoma and ocular hypertension. An investigator-sponsored Phase I/II dose-escalation study is ongoing to assess the safety and efficacy of the Latanoprost Product in patients with elevated intraocular pressure. We granted Pfizer an exclusive option, under various circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

We are investigating the use of Durasert technology for the treatment of orthopedic diseases.

*BioSilicon*. BioSilicon, the second key technology platform we are targeting for sustained drug delivery, utilizes fully-erodible, nanostructured, porous material. Our primary focus is on Tethadur, which utilizes BioSilicon to deliver large biologic molecules, including peptides and proteins, on a sustained basis. The sizes of the pores in the BioSilicon material are manufactured using nanotechnology to accommodate specific protein, peptide or antibody molecules. These molecules are then released and the material erodes slowly over time. Our BioSilicon technology can also be designed to deliver smaller molecules. We are investigating the use of BioSilicon in our Latanoprost Product and the use of Tethadur in other ophthalmic applications.

FDA Approved Products. Our two FDA-approved products, Retisert for the treatment of posterior uveitis and Vitrasert for the treatment of AIDS-related cytomegalovirus retinitis, are surgically implanted. They are both licensed to Bausch & Lomb.

Durasert<sup>™</sup>, BioSilicon<sup>™</sup> and Tethadur<sup>™</sup> are our trademarks. Retisert<sup>®</sup> and Vitrasert<sup>®</sup> are Bausch & Lomb's trademarks, and ILUVIEN<sup>®</sup> and FAME<sup>™</sup> are Alimera's trademarks.

#### **Critical Accounting Policies and Estimates**

The preparation of consolidated financial statements in conformity with GAAP requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates, judgments and assumptions on historical experience, anticipated results and trends, and on various other factors that we believe are reasonable under the circumstances at the time. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty. Actual results may differ from our estimates under different assumptions or conditions. In our Annual Report on Form 10-K for the year ended June 30, 2012 ("fiscal year 2012"), we set forth our critical accounting policies and estimates, which included revenue recognition and valuation of our intangible assets. There have been no material changes to our critical accounting policies from the information provided in our Annual Report on Form 10-K for fiscal year 2012.

#### **Results of Operations**

Three Months Ended September 30, 2012 Compared to Three Months Ended September 30, 2011:

	Three Months Ended September 30,		Change	
	2012	2011	Amounts	%
	(1	(In thousands except percentages)		
Revenues	\$ 553	\$ 1,659	\$(1,106)	(67)%
Operating expenses:				
Research and development	1,523	2,129	(606)	(28)%
General and administrative	1,620	2,061	(441)	(21)%
Total operating expenses	3,143	4,190	(1,047)	(25)%
Loss from operations	(2,590)	(2,531)	(59)	(2)%
Other income (expense):				
Change in fair value of derivatives	—	42	(42)	(100)%
Interest income	7	9	(2)	(22)%
Other expense, net	(1)	(2)	1	50%
Total other income	6	49	(43)	(88)%
Loss before income taxes	(2,584)	(2,482)	(102)	(4)%
Income tax benefit	33	55	(22)	(40)%
Net loss	\$(2,551)	\$(2,427)	\$ (124)	(5)%

#### Revenues

Revenues decreased by \$1.1 million, or 67%, to \$553,000 for the three months ended September 30, 2012 from \$1.7 million for the three months ended September 30, 2011. Collaborative research and development revenue decreased principally as a result of \$1.1 million recognized in the prior year period due to the July 2011 termination by Intrinsiq of its exclusive field-of-use license for nutraceutical and food science applications of BioSilicon. Royalty income totaled \$384,000 for the three months ended September 30, 2012 compared to \$198,000 for the three months ended September 30, 2011 as a result of increased Retisert royalties from Bausch & Lomb.

Alimera reported that it expects to begin generating revenue from sales of ILUVIEN for DME in the EU during the first quarter of 2013. Under the Alimera Agreement, we will be entitled to 20% of net profits, as defined, on a country-by-country basis. We do not know when and if Alimera will achieve net profits in each EU country where it has marketing approval and intends to commercialize ILUVIEN directly. Alimera also reported that, based on a June 2012 meeting with the FDA, it intends to resubmit its NDA for ILUVIEN for DME to the FDA. We would be entitled to receive a \$25.0 million milestone payment from Alimera within 30 days following any such FDA approval, although we do not know when or if that approval would occur.

#### **Research and Development**

Research and development decreased by \$606,000, or 28%, to \$1.5 million for the three months ended September 30, 2012 from \$2.1 million for the three months ended September 30, 2011. This decrease was primarily attributable to reduced amortization of intangible assets resulting from a \$14.8 million intangible asset impairment write-down at December 31, 2011. We may significantly increase our research and development expense during the remainder of fiscal year 2013, primarily dependent upon whether and when we initiate internally funded Phase III clinical trials of our sustained-release micro-insert to treat patients with posterior uveitis and Phase II clinical trials for the Latanoprost Product.

## General and Administrative

General and administrative decreased by \$441,000, or 21%, to \$1.6 million for the three months ended September 30, 2012 from \$2.1 million for the three months ended September 30, 2011. This decrease was primarily attributable to lower professional fees and stock-based compensation.

#### Change in Fair Value of Derivatives

Change in fair value of derivatives was \$0 for the three months ended September 30, 2012 compared to income of \$42,000 for the prior year's first quarter. This net decrease, determined using the Black-Scholes valuation model, was due to the expiration of the last of the A\$-denominated warrants in July 2012.

#### Income Tax Benefit

Income tax benefit was \$33,000 for the three months ended September 30, 2012 compared to \$55,000 for the quarter a year earlier. The net change was primarily attributable to a \$13,000 net reduction of deferred tax liabilities in the prior year period.

#### Liquidity and Capital Resources

During the past three fiscal years, we have financed our operations primarily from license fees, research and development funding and payment of a contingent note from our collaboration partners, and registered direct offerings of our common stock and warrants in January 2011 and August 2012. At September 30, 2012, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities totaling \$17.6 million. Our cash equivalents are predominantly invested in one institutional money market fund and our marketable securities are primarily invested in investment-grade corporate debt and commercial paper with maturities at September 30, 2012 ranging from zero to eight months.

With the exception of fiscal year 2010, we have incurred operating losses each year since inception and, at September 30, 2012, we had a total accumulated deficit of \$254.3 million. We generally expect negative cash flows from operations on a quarterly basis at least until such time as we receive sufficient revenues from ILUVIEN for DME or one or more of our product candidates achieves regulatory approval and provides us sufficient revenues. We believe that our capital resources of \$17.6 million at September 30, 2012 and expected royalty income from Bausch & Lomb should enable us to fund our operations as currently planned through the end of calendar year 2013, including plans for Phase III clinical trials of the posterior uveitis micro-insert. Whether we will require, or desire, to raise additional capital will be influenced by many factors, including, but not limited to:

- whether, when and to what extent we receive revenues from Alimera with respect to ILUVIEN for DME, including from commercialization in the EU or upon any approval or commercialization in the U.S.;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- when and if we initiate, how we conduct, and whether and the extent to which we internally fund product development and programs, including clinical trials for the posterior uveitis micro-insert and the Latanoprost Product, and ongoing research and development of BioSilicon technology applications;
- · whether and when Pfizer exercises its option with respect to the Latanoprost Product;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- · changes in our operating plan resulting in increases or decreases in our need for capital.

Absent adequate levels of funding from new and existing collaboration agreements and/or financing transactions, management currently believes that our cash position beyond calendar year 2013 depends significantly on possible revenues from the successful commercialization by Alimera of ILUVIEN for DME in the EU and if ILUVIEN for DME were to be approved by the FDA and successfully commercialized in the U.S. However, there is no assurance that the FDA or other regulatory authorities will approve ILUVIEN for DME, that it will achieve market acceptance in any market or that we will receive significant, if any, revenues from ILUVIEN for DME. Exercise by Pfizer of its option for the Latanoprost Product would also enhance our cash position, although there is no assurance when the option will become exercisable or if Pfizer will exercise it.

We enhanced our capital resources during the most recent quarter, raising net proceeds of \$4.7 million through a registered direct offering of common stock and warrants. 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. The state of the economy and the financial and credit markets at the time we seek additional financing may make it more difficult and more expensive to obtain. 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 research or development programs, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

Our consolidated statements of historical cash flows are summarized as follows:

		Three Months Ended September 30,	
	2012	2011	Change
		(In thousands)	
Net loss:	\$(2,551)	\$(2,427)	\$ (124)
Changes in operating assets and liabilities	295	(1,597)	1,892
Other adjustments to reconcile net loss to cash flows from operating activities	635	1,364	(729)
Net cash used in operating activities	\$(1,621)	\$(2,660)	\$1,039
Net cash provided by (used in) investing activities	\$ 647	\$ (552)	\$1,199
Net cash provided by financing activities	\$ 4,735	\$ 114	\$4,621

Net cash used in operating activities decreased by \$1.0 million to \$1.6 million for the three months ended September 30, 2012 compared to \$2.7 million for the prior year's quarter. The net decrease of cash used in operating activities consisted of a \$443,000 increase of collaborative research and development and royalty cash inflows and a net \$600,000 decrease in operating cash outflows, primarily related to the absence of cash incentive compensation related to fiscal year 2012, the payment of which is subject to future conditions, and lower research and development costs, partially offset by increased headcount.

Net cash provided by investing activities consisted principally of \$651,000 of maturities, net of purchases, of marketable securities during the three months ended September 30, 2012 compared to of \$331,000 of purchases, net of maturities, of marketable securities during the first quarter last year. Purchases of property and equipment totaling \$221,000 for the three months ended September 30, 2011 were attributable to the July 2011 asset purchase agreement with Intrinsiq.

We had no borrowings or line of credit facilities as of September 30, 2012.

#### **Off-Balance Sheet Arrangements**

We had no off-balance sheet arrangements as of September 30, 2012 that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that would be material to investors.

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

We have exposure to foreign currency exchange rates.

#### **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. The strengthening of the U.S. dollar during the three months ended September 30, 2012 compared to the prior year's quarter resulted in a net decrease in research and development expenses of approximately \$11,000. 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 impacted total stockholders' equity. As reported in the statement of operations and comprehensive loss, the weakening of the U.S. dollar in relation to the Pound Sterling at September 30, 2012 compared to June 30, 2012 resulted in a net increase of approximately \$59,000 in stockholders' equity due to the translation of approximately £1.0 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 September 30, 2012 in relation to the Pound Sterling, our stockholders' equity at September 30, 2012 would have decreased or increased, respectively, by approximately \$85,000.

#### **Item 4. Controls and Procedures**

## **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2012, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control over Financial Reporting**

During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II: OTHER INFORMATION

#### Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in Part I, "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended June 30, 2012.

# Item 6. Exhibits

- 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
- 101 The following materials from pSivida Corp.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss; (iii) Condensed Consolidated Statement of Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements



# 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: November 9, 2012

# pSivida Corp.

By: /s/ Paul Ashton

Name: Paul Ashton

Title: President and Chief Executive Officer

# 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: November 9, 2012

/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.;
- 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: November 9, 2012

/s/ Leonard S. Ross

Name: Leonard S. Ross Title: Vice President, Finance (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 September 30, 2012, 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: November 9, 2012

/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 September 30, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard S. Ross, Vice President, Finance 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: November 9, 2012

/s/ Leonard S. Ross

Name: Leonard S. Ross Title: Vice President, Finance (Principal Financial Officer)