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, 2011

OR

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

For the transition period from

COMMISSION FILE NUMBER 000-51122

to



(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 \square No \square

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 \Box

Non-accelerated filer \Box

Smaller reporting company

 \times

Accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 🗌 No 🗵

There were 20,802,592 shares of the registrant's common stock, \$0.001 par value, outstanding as of November 4, 2011.

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)

	September 30, 2011	June 30, 2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,811	\$ 12,912
Marketable securities	11,460	11,216
Accounts and other receivables	723	843
Prepaid expenses and other current assets	286	395
Total current assets	22,280	25,366
Property and equipment, net	397	123
Intangible assets, net	20,387	21,564
Other assets	76	60
Total assets	\$ 43,140	\$ 47,113
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 511	\$ 328
Accrued expenses	845	1,322
Deferred revenue	2,509	3,212
Derivative liabilities	128	170
Total current liabilities	3,993	5,032
Deferred revenue	3,915	4,635
Deferred tax liabilities		13
Total liabilities	7,908	9,680
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, 20,802,592 and 20,748,642 shares issued and outstanding at September 30, 2011 and June 30, 2011, respectively	21	21
Additional paid-in capital	263,497	262,906
Accumulated deficit	(229,350)	(226,923)
Accumulated other comprehensive income	1,064	1,429
Total stockholders' equity	35,232	37,433
Total liabilities and stockholders' equity	\$ 43,140	\$ 47,113

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See notes to condensed consolidated financial statements

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

	Three Mor Septem	
	2011	2010
Revenues:		
Collaborative research and development	\$ 1,461	\$ 74
Royalty income	198	402
Total revenues	1,659	476
Operating expenses:		
Research and development	2,129	1,742
General and administrative	2,061	2,169
Total operating expenses	4,190	3,911
Loss from operations	_ (2,531)	(3,435)
Other income (expense):		
Change in fair value of derivatives	42	338
Interest income	9	6
Other expense, net	(2)	(8)
Total other income	49	336
Loss before income taxes	(2,482)	(3,099)
Income tax benefit (expense)	55	(9)
Net loss	<u>\$ (2,427)</u>	\$ (3,108)
Basic and diluted net loss per share	<u>\$ (0.12)</u>	\$ (0.17)
Weighted average common shares outstanding:		
Basic and diluted	20,757	18,531

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	Stock Par Value <u>Amount</u>	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at July 1, 2011	20,748,642	\$ 21	\$262,906	\$ (226,923)	\$ 1,429	\$ 37,433
Comprehensive loss:						
Net loss				(2,427)		(2,427)
Foreign currency translation adjustments				_	(363)	(363)
Net unrealized loss on marketable securities	—		—	_	(2)	(2)
Total comprehensive loss						<u>\$ (2,792)</u>
Exercise of stock options	53,950		114			114
Stock-based compensation		<u> </u>	477			477
Balance at September 30, 2011	20,802,592	\$ 21	\$263,497	\$ (229,350)	\$ 1,064	\$ 35,232

See notes to condensed consolidated financial statements

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

	Three Mon Septem 2011	
Cash flows from operating activities:		
Net loss	\$ (2,427)	\$ (3,108)
Adjustments to reconcile net loss to cash flows from operating activities:		
Amortization of intangible assets	833	811
Depreciation of property and equipment	24	10
Change in fair value of derivatives	(42)	(338)
Stock-based compensation expense	477	451
Amortization of bond premium on marketable securities	85	29
Deferred tax benefit	(13)	
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	206	(251)
Accounts payable and accrued expenses	(373)	(303)
Deferred revenue	(1,430)	480
Net cash used in operating activities	(2,660)	(2,219)
Cash flows from investing activities:		
Purchases of marketable securities	(3,731)	(3,466)
Maturities of marketable securities	3,400	300
Purchases of property and equipment	(221)	(9)
Net cash used in investing activities	(552)	(3,175)
Cash flows from financing activities:		
Exercise of stock options	114	
Net cash provided by financing activities	114	
Effect of foreign exchange rate changes on cash and cash equivalents	(3)	6
Net decrease in cash and cash equivalents	(3,101)	(5,388)
Cash and cash equivalents at beginning of period	12,912	15,514
Cash and cash equivalents at end of period	\$ 9,811	\$10,126
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	<u>\$ </u>	\$ 50
Supplemental disclosure of non-cash investing activities:		
Purchases of property and equipment	<u>\$88</u>	<u>\$ </u>

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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 months ended September 30, 2011 and 2010 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, 2011. 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, 2011, 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 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, 2011 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 currently focused on the treatment of chronic eye diseases utilizing its core technology systems, Durasert[™] and BioSilicon[™]. ILUVIEN® for the treatment of diabetic macular edema ("DME"), the Company's lead product candidate, is under review by the U.S. Food and Drug Administration ("FDA"). An investigator-sponsored Investigational New Drug ("IND") opened for an injectable insert designed to treat posterior uveitis of the same design as ILUVIEN and an investigator-sponsored trial is ongoing for an injectable bioerodible insert designed to treat glaucoma and ocular hypertension.

ILUVIEN is licensed to Alimera Sciences, Inc. ("Alimera"), which completed two Phase III clinical trials (the "FAMETM Study"). Alimera submitted a New Drug Application ("NDA") for ILUVIEN for DME to the FDA in June 2010 based on month 24 data from the FAME Study and received a Complete Response Letter ("CRL") in December 2010. In the CRL, the FDA communicated its decision that the NDA could not be approved in its then present form. The FDA asked for analyses of the safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. The FDA also sought additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN. Alimera reported that in a February 2011 meeting with the FDA to review the CRL, the FDA requested specific additional data related to the use of the commercial version of the ILUVIEN inserter for which approval was sought in the NDA. In May 2011, Alimera resubmitted an NDA to the FDA to respond to the CRL. Alimera reported that the FDA classified its response as a Class 2 resubmission, resulting in a six-month review period and a Prescription Drug User Fee Act or PDUFA date of November 12, 2011, and that in July 2011 the FDA notified Alimera that an advisory committee would not be called during this review. Alimera reported that in September 2011, it commenced enrollment of a Phase III physician utilization study aimed at providing the additional data requested by the FDA. Alimera reported that to date, 54 of the targeted 100 patient eyes have been enrolled in this study designed to assess the safety and utility of the new inserter. Data from this study may be required by the FDA for its consideration of the approval of ILUVIEN for DME. Alimera stated that if approved, it plans to commercialize ILUVIEN for DME in the U.S. as soon as early calendar year 2012.

In July 2010, Alimera submitted a Marketing Authorization Application for ILUVIEN for DME to the Medicines and Healthcare products Regulatory Agency ("MHRA") in the United Kingdom and to other regulatory authorities in Europe. In November 2010, Alimera received the Preliminary Assessment Report from the MHRA, followed by additional comments from the other health authorities in December 2010. In July 2011, Alimera submitted its draft responses to the clinical, non-clinical and quality questions to the MHRA, including the additional safety and efficacy data through the final readout at the end of the FAME Study. Alimera reported that, in September 2011, the MHRA provided comments to Alimera's clinical responses and indicated that there were no further comments to Alimera's non-clinical and quality responses. Alimera has reported that it plans to submit in November 2011 its final response to the Preliminary Assessment Report from the MHRA and to the additional comments from the other regulatory authorities.

In June 2011, the Company amended and restated its 2007 collaborative research and license agreement with Pfizer, Inc. ("Pfizer") to focus solely on the development of an injectable bioerodible sustained-release Durasert implant to deliver latanoprost for human ophthalmic disease or conditions, other than uveitis. The Company granted

Pfizer an exclusive option, under various circumstances, to license the development and commercialization of this product worldwide. The Company is currently developing a prototype of this implant that contains BioSilicon to assist in the delivery of latanoprost.

The Company's two FDA-approved products utilize earlier generations of the Durasert technology system, second-generation Retisert® for the treatment of posterior uveitis and first-generation Vitrasert® for the treatment of AIDS-related cytomegalovirus retinitis. Both of these products and the technologies underlying them are licensed to Bausch & Lomb Incorporated ("Bausch & Lomb").

BioSilicon, the Company's other principal technology system, is a fully-erodible, nanostructured porous silicon designed to provide sustained delivery of various therapeutics, including proteins and peptides. Based on results of its preliminary studies, the Company is currently targeting BioSilicon as a second key drug delivery technology.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, its ability, and that of its collaboration partners, to successfully advance research, pre-clinical and clinical development, obtain regulatory approvals and commercialize product candidates utilizing the Company's technologies, development by its competitors and others of alternative products and disease treatments, ability to protect its proprietary technologies, dependence on key personnel, compliance with FDA and other governmental regulations and approval requirements, as well as its ability to execute on its business strategies and obtain adequate financing to fund its operations through collaborations, sales of equity or otherwise.

The Company expects its future operating results will vary from year to year and quarter to quarter, and such variations could be significant. Future operating results are expected to depend, among other things, upon the amounts of payments received from, and revenue recognition associated with, the Company's current and any potential future collaboration arrangements, its clinical research and development and other costs and outcomes of its product candidates. The Company anticipates that its capital resources of \$21.3 million at September 30, 2011 should enable the Company to maintain its current and planned operations into at least calendar year 2013. The Company's ability to fund its planned operations internally beyond then may be substantially dependent upon whether and when the FDA approves ILUVIEN for DME, which would result in a \$25.0 million milestone payment due from Alimera, as well as the extent to which Alimera is able to successfully commercialize ILUVIEN for DME.

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.

2. License and Collaboration Agreements

Alimera Sciences, Inc.

Under a collaboration agreement with Alimera, as amended in March 2008 (the "Alimera Agreement"), the Company has licensed Alimera the rights to develop, market and sell certain products, including ILUVIEN.

Upon execution of the Alimera Agreement in March 2008, the Company received consideration of \$12.0 million in cash and Alimera cancelled \$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. In addition, the Company received a \$15.0 million interest-bearing conditional note (subject to acceleration upon the occurrence of certain defined liquidity events), Alimera agreed to pay a \$25.0 million milestone payment upon FDA approval of ILUVIEN for DME, and Alimera assumed all financial responsibility for the development of licensed products under the Alimera Agreement, which had previously been shared equally, including reimbursement of approved development costs incurred by the Company in support of the ongoing clinical studies of ILUVIEN for DME and anticipated regulatory submissions. In exchange, the Company decreased its share in any future profits, as defined, on sales of ILUVIEN for DME by Alimera from 50% to 20%, subject to an offset of 20% of pre-profitability commercialization costs, as defined, incurred by Alimera. In the event Alimera sublicenses commercialization, the Company is entitled to receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. On April 27, 2010, following consummation of its initial public offering, Alimera paid the \$15.0 million conditional note in full together with \$225,000 of accrued and unpaid interest.

Revenue related to the Alimera Agreement totaled approximately \$31,000 and \$54,000 during the three months ended September 30, 2011 and 2010, 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 its technologies in ophthalmic applications that were not licensed to others. Commencing in calendar year 2008, Pfizer paid the Company \$500,000 quarterly in consideration of the Company's costs in performing the research program.

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 a sustained-release bioerodible implant designed to deliver latanoprost for human ophthalmic disease or conditions, other than uveitis (the "Latanoprost Product"). The Original Pfizer Agreement was effectively terminated, including the cessation of Pfizer's \$500,000 quarterly funding of the research program. Upon execution of the Restated Pfizer Agreement, Pfizer made an upfront payment of \$2.3 million and 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"). An investigator-sponsored Phase I/II dose-escalation study has been initiated to assess the safety and efficacy of this insert for patients with ocular hypertension and glaucoma. 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 still 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 comm

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 (the "R&D program") and participation on a Joint Steering Committee ("JSC"). The Company concluded that the Pfizer exercise option for the worldwide exclusive license was not a deliverable of the arrangement, due to it being a substantive option and not being priced at a significant and incremental discount. The Company determined that the JSC did not have standalone value from the R&D program and therefore 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 has estimated to be 3 years.

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. The estimated selling price of \$6.7 million is being recognized as collaborative research and development revenue over the expected 3-year performance period using the proportional performance method. The Company recorded revenue of \$288,000 for the three months ended September 30, 2011 and \$0 for the three months ended September 30, 2010. At September 30, 2011 and June 30, 2011, the Company recorded deferred revenue of \$6.4 million and \$6.7 million, respectively, classified between current and non-current deferred revenue. The costs associated with conducting the research program for the Latanoprost Product are reflected in operating expenses in the period in which they are incurred.

To the extent that any subsequent payment is 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 amount 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.

On July 22, 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 exclusive field-of-use license to develop and commercialize nutraceutical and food science applications of BioSilicon. 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 collaborative research and development revenue of \$20,000.

Bausch & Lomb

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

Royalty income totaled \$198,000 and \$402,000 for the three months ended September 30, 2011 and 2010, respectively. Accounts receivable from Bausch & Lomb totaled \$198,000 and \$321,000 at September 30, 2011 and June 30, 2011, respectively.

3. Intangible Assets

The reconciliation of intangible assets for the three months ended September 30, 2011 and for the year ended June 30, 2011 is as follows:

Three Months Ended September 30, 2011 (In thousa	Year Ended June 30, 2011 nds)
\$ 55,422	\$ 53,275
(891)	2,147
54,531	55,422
(33,858)	(29,398)
(833)	(3,302)
547	(1,158)
(34,144)	(33,858)
\$ 20,387	\$ 21,564
	September 30, 2011 (In thousa \$ 55,422 (891) 54,531 (33,858) (833) 547 (34,144)

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 \$833,000 and \$811,000 for the three months ended September 30, 2011 and 2010, respectively. The carrying value of intangible assets at September 30, 2011 of \$20.4 million will be amortized on a straight-line basis over the remaining estimated useful life of 6.25 years, or approximately \$3.3 million per year. Of the total net book value at September 30, 2011, approximately \$6.6 million was attributable to the Durasert technology and \$13.8 million was attributable to the BioSilicon technology.

4. Marketable Securities

The amortized cost, unrealized (loss) gain and fair value of the Company's available-for-sale marketable securities at September 30, 2011 and June 30, 2011 were as follows:

	September 30, 2011				
	Amortized Cost	Unrealized Loss	Fair Value		
	Cost	(In thousands)	Pair Value		
Corporate bonds	\$ 6,974	\$ (15)	\$ 6,959		
U.S. Government obligations	1,953		1,953		
Commercial Paper	2,548	—	2,548		
Total marketable securities	\$ 11,475	<u>\$ (15)</u>	\$ 11,460		
		June 30, 2011			
	Amortized Cost	Unrealized (Loss) Gain	Fair Value		
		Unrealized	Fair Value		
Corporate bonds		Unrealized (Loss) Gain	Fair Value \$ 7,312		
Corporate bonds U.S. Government obligations	Cost	Unrealized (Loss) Gain (In thousands)			
1	<u>Cost</u> \$ 7,326	Unrealized (Loss) Gain (In thousands)	\$ 7,312		

During the three months ended September 30, 2011, approximately \$3.7 million of marketable securities were purchased and \$3.4 million matured. At September 30, 2011, the marketable securities had maturities ranging between one and ten months, with a weighted average maturity of 4.7 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, 2011 and June 30, 2011, 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 Company's derivative liabilities are classified as Level 3 and valued using the Black-Scholes model.

The following table summarizes the Company's assets and liabilities carried at fair value measured on a recurring basis at September 30, 2011 and June 30, 2011 by valuation hierarchy:

				Septeml	ber 30, 2011			
	,	al Carrying Value at mber 30, 2011	acti	ted prices in ve markets Level 1)	observ	ficant other vable inputs Level 2)	unobserv	nificant vable inputs evel 3)
				(In th	iousands)			
Assets:								
Cash equivalents	\$	8,479	\$	8,029	\$	450	\$	_
Marketable securities								
Corporate bonds		6,959		6,138		821		_
U.S. Government obligations		1,953				1,953		_
Commercial paper		2,548				2,548		_
	\$	19,939	\$	14,167	\$	5,772	\$	
Liabilities:								
Derivative liabilities	\$	128	\$		\$		\$	128

				Jun	e 30, 2011			
	,	al Carrying Value at ne 30, 2011	activ	ed prices in ve markets Level 1) (In t	observ	ficant other vable inputs Level 2)	unobserv	nificant vable inputs evel 3)
Assets:								
Cash equivalents	\$	8,678	\$	8,678	\$		\$	_
Marketable securities								
Corporate bonds		7,312		5,792		1,520		—
U.S. Government obligations		1,205				1,205		
Commercial paper		2,699		_		2,699		
	\$	19,894	\$	14,470	\$	5,424	\$	
Liabilities:								
Derivative liabilities	\$	170	\$	_	\$	_	\$	170

The Company's derivative liabilities were classified as Level 3 and valued using the Black-Scholes model. At September 30, 2011 and June 30, 2011, the fair values were derived by applying the following assumptions:

	September 30, 2011	<u>June 30, 2011</u>
Expected term (in years)	0.80	1.05
Stock volatility	90%	95%
Risk-free interest rate	0.10%	0.19%
Expected dividends	0%	0%

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 September 30,			
	2011	2010		
		(In thousands)		
Balance at beginning of period	\$ 170	\$	1,310	
Change in fair value of derivative - other income	 42		338	
Balance at end of period	\$ 128	\$	972	

6. Stockholders' Equity

Warrants to Purchase Common Shares

The following table provides a reconciliation of all US\$ warrants for the three months ended September 30, 2011 and 2010:

	Т	Three Months Ended September 30,			
	2011	2011)	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price	
Balance at beginning of period	7,614,748	\$ 7.35	7,062,248	\$ 7.53	
Expired	(2,281,250)	7.50			
Balance and exercisable at end of period	5,333,498	\$ 7.29	7,062,248	\$ 7.53	

At September 30, 2011, the remaining term of these outstanding warrants ranged from 0.1 to 4.3 years, representing a weighted average period of 1.0 year.

At September 30, 2011, the Company had 205,479 warrants outstanding denominated in A\$ with an exercise price of A\$7.68 and a weighted average remaining life of 9.5 months. At September 30, 2010, the Company had 3,935,433 warrants outstanding with a weighted average exercise price of A\$9.54. The weighted average exercise price of these warrants translated to US\$ was \$7.52 at September 30, 2011 and \$9.25 at September 30, 2010. During the three months ended September 30, 2011 and 2010, there were no warrants issued or exercised.

Because the potential exercise of the A\$-denominated 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, subject to revaluation of the liability on a recurring basis through the statement of operations.

2008 Incentive Plan

The Company's 2008 Incentive Plan (the "2008 Plan") provides for the issuance of a maximum of 4,091,255 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, 2011:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2011	2,605,895	\$ 2.63		
Granted	357,350	5.05		
Exercised	(53,950)	2.12		
Forfeited	(41,919)	3.45		
Outstanding at September 30, 2011	2,867,376	\$ 2.93	8.04	\$ 4,114
Outstanding at September 30, 2011 - vested or unvested and expected to vest	2,720,900	\$ 2.90	8.00	\$ 3,978
Exercisable at September 30, 2011	1,378,034	\$ 2.46	7.59	\$ 2,497

Option grants for the three months ended September 30, 2011 consisted of 297,350 options with ratable annual vesting over 4 years and 60,000 options subject to performance and service conditions. A total of 343,734 options vested during the three months ended September 30, 2011. All option grants have a 10-year contractual life.

In determining the grant date fair value of stock 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, 2011 based on the following key assumptions:

Expected term (in years)	3.50 - 6.25
Stock volatility	90%
Risk-free interest rate	0.91% - 2.02%
Expected dividends	0%

The following table summarizes information about stock options for the three months ended September 30, 2011:

Weighted-average grant date fair value, per share	\$3.69
Total cash received from exercise of stock options (in thousands)	114
Total intrinsic value of stock options exercised (in thousands)	119

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\$.

The following table provides a reconciliation of stock option activity under the Plan for the three months ended September 30, 2011:

	Number of Options	Weighted Average Exercise Price A\$	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value A\$
Outstanding at July 1, 2011	135,000	6.75		
Cancelled	(22,500)	13.00		
Outstanding and exercisable at September 30, 2011	112,500	5.50	1.00	

At September 30, 2011, translated into \$, the weighted average exercise price of outstanding and exercisable options was \$5.39.

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, 2011 and 2010, as follows:

	 Three Months Ended September 30,				
	2011	2	2010		
	(In thousands)				
Compensation expense included in:					
Research and development	\$ 147	\$	101		
General and administrative	330		350		
	 455	ф.	454		
	\$ 477	\$	451		

At September 30, 2011, there was approximately \$2.1 million of unrecognized compensation expense related to unvested share-based payment awards under the Company's option plans, 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 \$55,000 for the three months ended September 30, 2011, primarily related to earned foreign research and development tax credits.

For the three months ended September 30, 2011 and 2010, the Company had no significant unrecognized tax benefits in the accompanying unaudited condensed consolidated financial statements. At September 30, 2011 and June 30, 2011, 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 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 months ended September 30, 2011 and 2010 as their inclusion would be anti-dilutive.

Potentially dilutive shares at September 30, 2011 and 2010 were as follows:

	Septer	September 30,		
	2011	2010		
Options	2,979,876	2,500,320		
Warrants	5,538,977	10,997,681		
	8,518,853	13,498,001		

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: Alimera's ability to obtain regulatory approval of and successfully commercialize ILUVIEN for DME; risk/benefit profile of ILUVIEN for DME; timeliness of approval, if any, of ILUVIEN for DME and any limitations on uses thereof; ability to complete clinical trials, reference data and obtain regulatory approval of other product candidates; ability to raise capital if needed; ability to achieve profitability; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; ability to derive revenues from Retiser; ability to find partners to develop and market products; termination of license agreements; competition; market acceptance of products and product candidates; reduction in use of products as a result of future publications; ability to protect intellectual property or infringement of others' intellectual property; 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 pay any registration penalties; 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 forward-looking 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 drugs at a controlled and steady rate for months or years. We are currently focused on treatment of chronic diseases of the back of the eye utilizing our core technology systems, Durasert[™] and BioSilicon[™]. ILUVIEN® for the treatment of diabetic macular edema ("DME"), our lead product candidate, is currently under review by the U.S. Food and Drug Administration ("FDA"). An investigator-sponsored Investigational New Drug ("IND") opened for an injectable insert designed to treat posterior uveitis of the same design as ILUVIEN and an investigator-sponsored trial is ongoing for an injectable bioerodible insert delivering latanoprost to treat glaucoma and ocular hypertension. Our two FDA-approved products provide long-term, sustained drug delivery to treat other chronic diseases of the retina.

ILUVIEN. We licensed the third generation injectable Durasert insert that delivers the corticosteroid fluocinolone acetonide ("FAC") over a period of up to 3 years to Alimera for the treatment and prevention of eye diseases in humans (other than uveitis). This insert is being developed by Alimera under its brand name ILUVIEN. Alimera completed two Phase III clinical trials ("FAMETM Study") of ILUVIEN for the treatment of DME, a leading cause of vision loss for people under the age of 65 estimated to affect over 1,000,000 people in the United States.

Alimera submitted a New Drug Application (" NDA") for ILUVIEN for DME to the FDA in June 2010 based on month 24 data from the FAME Study and received a Complete Response Letter ("CRL") in December 2010. In the CRL, the FDA communicated its decision that the NDA could not be approved in its then present form. The FDA asked for analyses of the safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. The FDA also sought additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN. Alimera reported that in a February 2011 meeting with the FDA to review the CRL, the FDA requested specific additional data related to the use of the commercial version of the ILUVIEN inserter for which approval was sought in the NDA. In May 2011, Alimera resubmitted an NDA to the FDA to respond to the CRL. Alimera reported that the FDA classified its response as a Class 2 resubmission, resulting in a six-month review period and a Prescription Drug User Fee Act or PDUFA date of November 12, 2011, and that in July 2011 the FDA notified Alimera that an advisory committee would not be called during this review. Alimera reported that in September 2011, it commenced enrollment of a Phase III physician utilization study aimed at providing the additional data requested by the FDA. Alimera reported that to date, 54 of the targeted 100 patient eyes have been enrolled in this study designed to assess the safety and utility of the new inserter. Data from this study may be required by the FDA for its consideration of the approval of ILUVIEN for DME. Alimera stated that if approved, it plans to commercialize ILUVIEN for DME in the U.S. as soon as early calendar year 2012.

In July 2010, Alimera submitted a Marketing Authorization Application for ILUVIEN for DME to the Medicines and Healthcare products Regulatory Agency ("MHRA") in the United Kingdom and to other regulatory authorities in Europe. In November 2010, Alimera received the Preliminary Assessment Report from the MHRA, followed by additional comments from the other health authorities in December 2010. In July 2011, Alimera submitted its draft responses to the clinical, non-clinical and quality questions to the MHRA, including the additional safety and efficacy data through the final readout at the end of the FAME Study. Alimera reported that, in September 2011, the MHRA provided comments to Alimera's clinical responses and indicated that there were no further comments to Alimera's non-clinical and quality responses. Alimera has reported that it plans to submit in November 2011 its final response to the Preliminary Assessment Report from the MHRA and to the additional comments from the other regulatory authorities.

Under our collaboration agreement with Alimera, in addition to treating DME, ILUVIEN is also being studied in three Phase II clinical trials for the treatment of both the dry and wet forms of Age-Related Macular Degeneration and Retinal Vein Occlusion.

Other Product Development. In September 2011, an investigator-sponsored IND opened for a Phase I/II study of the safety and efficacy of our injectable, sustained release insert delivering FAc for the treatment of uveitis affecting the posterior segment of the eye ("posterior uveitis"). If successful, we plan to advance this product candidate into pivotal multi-center Phase III trials and reference the NDA for ILUVIEN for DME (including the clinical data from the FAME Study and the manufacturing and stability data) in potential posterior uveitis regulatory filings. The insert is the same design as the insert being developed by Alimera for the treatment of DME and delivers the high and low dose of FAc used in the FAME Study. We did not license Alimera the rights to use the insert for uveitis. We also plan to design a different inserter, with a smaller gauge needle than that used in the FAME Study, in any future posterior uveitis Phase III trials.

Under our Restated Pfizer Agreement, we granted Pfizer an exclusive option under various circumstances to license the development and commercialization worldwide of an injectable, bioerodible sustained release insert delivering latanoprost for the treatment of human ophthalmic disease or conditions, other than uveitis ("Latanoprost Product"). An investigator-sponsored Phase I/II dose-escalation study has been initiated to assess the safety and efficacy of this insert, which utilizes a fourth generation of our Durasert technology, in patients with elevated intraocular pressure. We are currently developing a prototype of this insert that contains BioSilicon to assist in the delivery of latanoprost. If successful, we plan to advance the new prototype into a multi-center Phase II trial.

In August 2011, we entered into an evaluation agreement with Hospital for Special Surgery to investigate our Durasert drug delivery technologies in orthopedics.

Approved Products. Our two FDA-approved products utilize two earlier generations of our Durasert technology system, second-generation Retisert for the treatment of posterior uveitis, and first-generation Vitrasert for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb. Retisert delivers FAc to provide sustained release treatment for approximately two and a half years, and Vitrasert delivers ganciclovir to provide sustained release treatment for six to nine months.

BioSilicon. BioSilicon, the second key technology system we are targeting for sustained drug delivery, utilizes fully-erodible, nanostructured, porous material. Our primary focus is on TethadurTM, which utilizes BioSilicon to deliver large biologic molecules, including peptides and proteins, on a sustained basis. Our BioSilicon technology is also designed to deliver smaller molecules.

Medidur^M, Durasert^M, BioSilicon^M and Tethadur^M are our trademarks. Retisert[®] and Vitrasert[®] are Bausch & Lomb's trademarks, and ILUVIEN[®] and FAME^M 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, 2011 ("fiscal year 2011"), 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 2011.

Results of Operations

Three Months Ended September 30, 2011 Compared to Three Months Ended September 30, 2010:

	Three Mor Septem		Chang	že	
	2011	2010	Amounts	%	
	(In thousands except percentages)				
Revenues	\$ 1,659	\$ 476	\$ 1,183	249%	
Operating expenses:					
Research and development	2,129	1,742	387	22%	
General and administrative	2,061	2,169	(108)	(5)%	
Total operating expenses	4,190	3,911	279	7%	
Loss from operations	(2,531)	(3,435)	904	26%	
Other income (expense):					
Change in fair value of derivatives	42	338	(296)	(88)%	
Interest income	9	6	3	50%	
Other expense, net	(2)	(8)	6	75%	
Total other income	49	336	(287)	(85)%	
Loss before income taxes	(2,482)	(3,099)	617	20%	
Income tax benefit (expense)	55	(9)	64	711%	
Net loss	\$(2,427)	\$(3,108)	\$ 681	%	

Revenues

Revenues increased by \$1.2 million, or 249%, to \$1.7 million for the three months ended September 30, 2011 from \$476,000 for the three months ended September 30, 2010, primarily as a result of recognition of deferred collaborative research and development revenues. Collaborative research and development revenue, which totaled \$1.5 million for the three months ended September 30, 2011, consisted primarily of (i) \$288,000, representing a portion of the estimated \$6.7 million selling price associated with the Restated Pfizer Agreement, which is being recognized over the expected 3-year performance period using the proportional performance method and (ii) \$1.1 million, representing the total Intrinsiq deferred revenue balance at June 30, 2011, which was recognized 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 \$198,000 for the three months ended September 30, 2011 compared to \$402,000 for the three months ended September 30, 2010 as a result of decreased Retisert royalties from Bausch & Lomb.

If the FDA were to approve ILUVIEN for DME, we would be entitled to receive a \$25.0 million milestone payment from Alimera within 30 days following approval. Absent FDA approval of ILUVIEN for DME during fiscal year 2012, we currently expect that collaborative research and development revenue for the remainder of fiscal year 2012 will be predominantly attributable to continued recognition of the deferred revenue under the Restated Pfizer Agreement.

Research and Development

Research and development increased by \$387,000, or 22%, to \$2.1 million for the three months ended September 30, 2011 from \$1.7 million for the three months ended September 30, 2010. This increase was primarily attributable to costs of the Latanoprost Product Phase I/II clinical trial and increased personnel expense.

General and Administrative

General and administrative decreased by \$108,000, or 5%, to \$2.1 million for the three months ended September 30, 2011 from \$2.2 million for the three months ended September 30, 2010. This decrease was primarily attributable to lower professional fees.

Change in Fair Value of Derivatives

Change in fair value of derivatives represented income of \$42,000 for the three months ended September 30, 2011 compared to income of \$338,000 for the three months ended September 30, 2010. This net decrease, determined using the Black-Scholes valuation model, was primarily due to the expiration of approximately 3.7 million, or 95%, of the A\$-denominated warrants during fiscal year 2011.

Detachable warrants issued in share offerings denominated in A\$ were recorded as derivative liabilities, subject to revaluation at each subsequent balance sheet date, and changes in their fair values will result in adjustments to our recorded derivative liabilities (\$128,000 at September 30, 2011) and a corresponding income or expense in our statement of operations. Fluctuations in the fair values of these warrants will continue to affect our operating results until the last-to-expire of these warrants in July 2012.

Income Tax Benefit (Expense)

Income tax benefit of \$55,000 for the three months ended September 30, 2011 compared to income tax expense of \$9,000 for the three months ended September 30, 2010. The net change was primarily attributable to (i) the absence in the current year period of \$50,000 of U.S. federal alternative minimum tax expense in the prior year period and (ii) a \$13,000 net reduction of deferred tax liabilities.

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 a January 2011 registered direct offering of our common stock and warrants. At September 30, 2011, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities totaling \$21.3 million. Our cash equivalents are predominantly invested in one institutional money market fund and our marketable securities are invested in investment-grade corporate debt, government agency securities and commercial paper with maturities at September 30, 2011 ranging from one to ten months.

With the exception of fiscal year 2010, we have incurred operating losses each year since inception and, at September 30, 2011, we had a total accumulated deficit of \$229.4 million. 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 sufficient revenues from commercialization. We believe we can fund our operations as currently conducted into at least calendar year 2013. Whether we will require, or desire, to raise additional capital will be influenced by many other factors, including, but not limited to:

 the timely development, regulatory approval and successful commercialization of ILUVIEN for DME and receipt of milestone, royalty and other payments;

- the scope and extent of our internally funded operations and programs, including the clinical trials for the Latanoprost Product and the posterior uveitis insert, and any new product candidates and any new business opportunities;
- our ability to establish and maintain strategic arrangements for products and 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 any patent claims; and
- changes in our operating plan, including the pursuit of any new business opportunities, which may affect 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 after 2012 depends significantly on whether and when ILUVIEN for DME is approved by the FDA and foreign regulatory authorities and upon the initiation and success of marketing of ILUVIEN for DME. However, there is no assurance that the FDA or other regulatory authorities will approve ILUVIEN for DME or when any such approvals will occur or that it will achieve market acceptance and be successfully commercialized, even if it is approved.

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 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 historical cash flows are summarized as follows:

		Three Months Ended September 30,		
	2011	2011 2010		
		(In thousands)		
Net loss:	\$(2,427)	\$(3,108)	\$ 681	
Changes in operating assets and liabilities	(1,597)	(74)	(1,523)	
Other adjustments to reconcile net loss to cash flows from operating activities	1,364	963	401	
Net cash used in operating activities	\$(2,660)	\$(2,219)	<u>\$ (441)</u>	
Net cash used in investing activities	\$ (552)	\$(3,175)	\$ 2,623	
Net cash provided by financing activities	<u>\$ 114</u>	<u>\$ </u>	\$ 114	

Net cash used in operating activities increased by \$441,000 to \$2.7 million for the three months ended September 30, 2011 compared to \$2.2 million for the three months ended September 30, 2010. The net increase of cash used in operating activities consisted of a \$127,000 decrease of collaborative research and development and royalty cash inflows and a net \$314,000 increase in operating cash outflows, primarily related to personnel costs and professional fees.

Net cash used in investing activities consisted principally of \$331,000 of purchases, net of maturities, of marketable securities during the three months ended September 30, 2011 compared to \$3.2 million of net purchases

of marketable securities during the three months ended September 30, 2010. Purchases of property and equipment totaling \$221,000 for the three months ended September 30, 2011 was attributable to the July 2011 asset purchase agreement with Intrinsiq.

We had no borrowings or line of credit facilities as of September 30, 2011.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2011 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 changes in the valuation of derivative liabilities, foreign currency exchange rates and interest rates.

Derivative Liabilities

At September 30, 2011, the balance of our derivative liabilities, which relates to warrants denominated in A\$, totaled \$128,000 and was determined using the Black-Scholes valuation model. The change in fair value of derivatives resulted in income of \$42,000 and \$338,000 for the three months ended September 30, 2011 and 2010, respectively.

During fiscal year 2011, approximately 3.7 million A\$ warrants expired. At September 30, 2011, there were 205,479 warrants outstanding with a remaining contractual life of 9.5 months and a US\$-equivalent exercise price of \$7.52 per share compared to the \$4.27 NASDAQ closing price of our common shares. Fluctuations in our share price and the US\$-equivalent exercise price of the warrants as a result of currency rate changes are the primary factors that impact the change in fair value of these derivative liabilities. The following table summarizes the sensitivity of our consolidated statement of operations for the three months ended September 30, 2011 to assumed increases or decreases of our share price at September 30, 2011:

	Decre	Decrease in Share Price			Increase in Share Price		
	-15%	-10%	-5%		+5%	+10%	+15%
		(In thousands)					
Change in fair value of derivatives - income (expense)	\$ 46	\$ 31	\$ 16	<u>\$ </u>	\$(17)	\$(36)	\$(55)

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 weakening of the U.S. dollar during the three months ended September 30, 2011 compared to the prior year quarter resulted in a net increase in research and development expenses of approximately \$38,000. 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 impact total stockholders' equity. At September 30, 2011, compared to June 30, 2011, the strengthening of the U.S. dollar in relation to the Pound Sterling resulted in a net decrease of approximately \$363,000 in stockholders' equity due to the translation of approximately £9.1 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, 2011 in relation to the Pound Sterling, our stockholders' equity at September 30, 2011 would have decreased or increased, respectively, by approximately \$710,000.

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

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, 2011. 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, 2011, 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, 2011.

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

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 8, 2011

pSivida Corp.

By: /s/ Paul Ashton

Name:Paul AshtonTitle:President and Chief Executive Officer

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: November 8, 2011

/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 8, 2011

/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, 2011, 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 8, 2011

/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, 2011, 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 8, 2011

/s/ Leonard S. Ross

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