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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 December 31, 2011

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

pSivida Corp.
(Exact name of registrant as specified in its charter)

Delaware	**26-2774444**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Pleasant Street Watertown, MA	**02472**
(Address of principal executive offices)	**(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 ☒ No ☐

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	☐	Smaller reporting company	☐

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 February 6, 2012.

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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)

	December 31, 2011	June 30, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 8,408	$ 12,912
Marketable securities	10,272	11,216
Accounts and other receivables	1,016	843
Prepaid expenses and other current assets	157	395
Total current assets	19,853	25,366
Property and equipment, net	423	123
Intangible assets, net	4,596	21,564
Other assets	76	60
Total assets	$ 24,948	$ 47,113
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 262	$ 328
Accrued expenses	650	1,322
Deferred revenue	1,722	3,212
Derivative liabilities	—	170
Total current liabilities	2,634	5,032
Deferred revenue	4,521	4,635
Deferred tax liabilities	—	13
Total liabilities	7,155	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 December 31, 2011 and June 30, 2011, respectively	21	21
Additional paid-in capital	263,662	262,906
Accumulated deficit	(246,810)	(226,923)
Accumulated other comprehensive income	920	1,429
Total stockholders' equity	17,793	37,433
Total liabilities and stockholders' equity	$ 24,948	$ 47,113

See notes to condensed consolidated financial statements

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2011	2010	2011	2010
Revenues:				
Collaborative research and development	$ 204	$ 88	$ 1,665	$ 162
Royalty income	426	326	624	728
Total revenues	630	414	2,289	890
Operating expenses:				
Research and development	1,992	1,534	4,121	3,276
General and administrative	1,451	2,001	3,512	4,170
Impairment of intangible assets	14,830	—	14,830	—
Total operating expenses	18,273	3,535	22,463	7,446
Loss from operations	(17,643)	(3,121)	(20,174)	(6,556)
Other income (expense):				
Change in fair value of derivatives	128	458	170	796
Interest income	11	6	20	12
Other expense, net	—	(3)	(2)	(11)
Total other income	139	461	188	797
Loss before income taxes	(17,504)	(2,660)	(19,986)	(5,759)
Income tax benefit (expense)	44	(35)	99	(44)
Net loss	$(17,460)	$ (2,695)	$(19,887)	$ (5,803)
Basic and diluted net loss per share:	$ (0.84)	$ (0.15)	$ (0.96)	$ (0.31)
Weighted average common shares outstanding:				
Basic and diluted	20,803	18,531	20,780	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 Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at July 1, 2011	20,748,642	$ 21	$262,906	$ (226,923)	$ 1,429	$ 37,433
Comprehensive loss:						
Net loss	—	—	—	(19,887)	—	(19,887)
Foreign currency translation adjustments	—	—	—	—	(514)	(514)
Net unrealized gain on marketable securities	—	—	—	—	5	5
Total comprehensive loss						$ (20,396)
Exercise of stock options	53,950	—	114	—	—	114
Stock-based compensation	—	—	642	—	—	642
Balance at December 31, 2011	20,802,592	$ 21	$263,662	$ (246,810)	$ 920	$ 17,793

See notes to condensed consolidated financial statements

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

	Six Months Ended December 31,	
	2011	2010
Cash flows from operating activities:		
Net loss	$ (19,887)	$ (5,803)
Adjustments to reconcile net loss to cash flows from operating activities:		
Impairment of intangible assets	14,830	—
Amortization of intangible assets	1,652	1,633
Depreciation of property and equipment	68	23
Change in fair value of derivatives	(170)	(796)
Stock-based compensation expense	642	899
Amortization of bond premium on marketable securities	161	66
Deferred tax benefit	(13)	—
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	38	263
Accounts payable and accrued expenses	(730)	(546)
Deferred revenue	(1,611)	1,459
Net cash used in operating activities	(5,020)	(2,802)
Cash flows from investing activities:		
Purchases of marketable securities	(6,915)	(6,028)
Maturities of marketable securities	6,599	750
Proceeds from sales of marketable securities	1,103	—
Purchases of property and equipment	(380)	(59)
Net cash provided by (used in) investing activities	407	(5,337)
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	(5)	2
Net decrease in cash and cash equivalents	(4,504)	(8,137)
Cash and cash equivalents at beginning of period	12,912	15,514
Cash and cash equivalents at end of period	$ 8,408	$ 7,377
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$100

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 December 31, 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 and six months ended December 31, 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®, the Company's lead product candidate based on its Durasert technology, is under review by the Medicines and Healthcare products Regulatory Agency ("MHRA") in the United Kingdom and certain other regulatory authorities in the European Union (the"EU") for the treatment of diabetic macular edema ("DME"). 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 "FAME™ Study") of ILUVIEN for the treatment of DME. On November 10, 2011, Alimera received a complete response letter ("CRL") from the U.S. Food and Drug Administration ("FDA") in response to the New Drug Application ("NDA") for ILUVIEN for DME resubmitted in May 2011. This resubmission followed the receipt by Alimera in December 2010 of a CRL with respect to Alimera's original June 2010 NDA. The FDA stated in the 2011 CRL that it was unable to approve Alimera's NDA because it did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA also stated in the 2011 CRL that Alimera will need to conduct two additional clinical trials to demonstrate that ILUVIEN is safe and effective for DME. Alimera reported that it will be requesting a meeting with the FDA to clarify next steps.

In July 2010, utilizing the Decentralized Procedure, Alimera submitted a Marketing Authorization Application for ILUVIEN for DME to the MHRA in the United Kingdom and to regulatory authorities in six other EU countries. Alimera has reported that it expects a decision regarding the approval of ILUVIEN for DME in the first half of 2012.

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 the drug 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 has two FDA-approved products that 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, including, but not limited to, its 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 and pre-clinical and clinical development of and obtain regulatory approvals for product candidates utilizing the Company's technologies and successfully commercialize them, including the ability of Alimera to receive approval for and successfully commercialize ILUVIEN for DME in the EU, 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's future operating results are expected to depend, among other things, upon the success of, consideration received from, and revenue recognition associated with, and costs of, product research, development and commercialization by the Company and its current and any potential future collaborative partners. The Company believes that its cash, cash equivalents and marketable securities of $18.7 million at December 31, 2011 together with expected royalty income should enable the Company to maintain its current and planned operations into at least the beginning of calendar year 2013. The Company may seek to obtain additional capital resources and/or reduce its capital requirements as the result of possible approval and marketing of ILUVIEN for DME in the EU; possible new collaborative, licensing or other agreements; possible adjustments to the Company's operating plan, including delaying initiation of clinical trials; and/or possible other agreements and transactions, which may include sales of assets or securities.

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 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. In April 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 $23,000 for the three months ended December 31, 2011 compared to $67,000 for last year's second quarter and $54,000 for the six months ended December 31, 2011 compared to $121,000 for the same period last year.

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 its 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 Product on its own or with a partner.

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 collaborative research and development revenue related to the Restated Pfizer Agreement of $182,000 for the three months ended December 31, 2011 and $470,000 for the six months ended December 31, 2011 compared to $0 for each of the three and six month periods ended December 31, 2010. At December 31, 2011 and June 30, 2011, the Company recorded deferred revenue of $6.2 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, under which it acquired 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, which had been classified as a current liability. The Company recognized Intrinsiq collaborative research and development revenue of $21,000 during the three months ended December 31, 2010 and $41,000 during the six months ended December 31, 2010.

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 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 the Retisert device) in return for royalties based on sales.

Royalty income totaled $426,000 for the three months ended December 31, 2011 compared to $326,000 for the prior year quarter and $624,000 for the six months ended December 31, 2011 compared to $728,000 for the prior year six month period. Accounts receivable from Bausch & Lomb totaled $426,000 at December 31, 2011 and $321,000 at June 30, 2011.

3. Intangible Assets

The reconciliation of intangible assets for the six months ended December 31, 2011 and for the year ended June 30, 2011 is as follows:

	Six Months Ended December 31, 2011	Year Ended June 30, 2011
	(In thousands)	
Patented technologies		
Gross carrying amount at beginning of period	$ 55,422	$ 53,275
Asset impairment write-down	(14,830)	—
Foreign currency translation adjustments	(1,280)	2,147
Gross carrying amount at end of period	39,312	55,422
Accumulated amortization at beginning of period	(33,858)	(29,398)
Amortization expense	(1,652)	(3,302)
Foreign currency translation adjustments	794	(1,158)
Accumulated amortization at end of period	(34,716)	(33,858)
Net book value at end of period	$ 4,596	$ 21,564

In the CRL received by Alimera from the FDA in November 2011, in response to Alimera's NDA for ILUVIEN for DME, the FDA stated that it was unable to approve the NDA because it did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME, that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials and that Alimera would need to conduct two additional clinical studies to demonstrate that ILUVIEN is safe and effective for DME. FDA approval of the NDA for ILUVIEN for DME would have resulted in receipt by the Company of a $25.0 million milestone payment from Alimera. Following the public announcement of the receipt 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 the balance sheet date. 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.

As of December 31, 2011, the forecasted probability-weighted undiscounted cash flows for the intangible assets were not expected to be sufficient to recover the aggregate carrying value of $19.4 million, consisting of $6.3 million for the Durasert technology and $13.1 million for the BioSilicon technology. To assess the recoverability of the combined intangible assets, management used a combination of market-based and income-based valuation methodologies. Using the market-based approach as the primary indicator of fair value, an enterprise value of $4.4 million (market capitalization less existing capital resources) was adjusted for an estimated control premium and for other working capital items to derive an implied fair value of the intangible assets of $4.6 million. Under the income-based approach, the forecasted cash flows expected for the intangible assets were discounted using after-tax cost of capital rates taking into account Company-specific risks. The resulting fair value under this approach supported the fair value determined under the market-based approach. Based on the above analyses, the fair value of the combined intangible assets has been allocated to each intangible based on the values determined under the income-based approach, as follows:

	Pre-impairment Carrying Value at December 31, 2011	Impairment Charge	Post-impairment Carrying Value at December 31, 2011
		(In thousands)	
Durasert	$ 6,318	$ (3,141)	$ 3,177
BioSilicon	13,108	(11,689)	1,419
	$ 19,426	$ (14,830)	$ 4,596

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 $819,000 for the three months ended December 31, 2011 compared to $822,000 for the prior year quarter and $1.7 million for the six months ended December 31, 2011 compared to $1.6 million for the prior year six-month period. The post-impairment carrying value of intangible assets at December 31, 2011 of $4.6 million is expected to be amortized on a straight-line basis over the remaining estimated useful life of 6 years, or approximately $765,000 per year.

4. Marketable Securities

The amortized cost, unrealized (loss) gain and fair value of the Company's available-for-sale marketable securities at December 31, 2011 and June 30, 2011 were as follows:

	December 31, 2011		
	Amortized Cost	Unrealized (Loss) Gain	Fair Value
	(In thousands)		
Corporate bonds	$ 5,881	$ (8)	$ 5,873
U.S. Government obligations	751	—	751
Commercial paper	2,698	1	2,699
Certificates of deposit	950	(1)	949
Total marketable securities	$ 10,280	$ (8)	$ 10,272

	June 30, 2011		
	Amortized Cost	Unrealized (Loss) Gain	Fair Value
	(In thousands)		
Corporate bonds	$ 7,326	$ (14)	$ 7,312
U.S. Government obligations	1,204	1	1,205
Commercial paper	2,699	—	2,699
Total marketable securities	$ 11,229	$ (13)	$ 11,216

During the six months ended December 31, 2011, $6.9 million of marketable securities were purchased and $7.7 million matured or were called by the issuers prior to scheduled maturity. At December 31, 2011, the marketable securities had maturities ranging between one and ten months, with a weighted average maturity of 4.0 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 December 31, 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 December 31, 2011 and June 30, 2011 by valuation hierarchy:

	December 31, 2011			
	Total Carrying Value at December 31, 2011	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	(In thousands)			
Assets:				
Cash equivalents	$ 7,774	$ 7,774	$ —	$ —
Marketable securities				
Corporate bonds	5,873	5,062	811	—
U.S. Government obligations	751	—	751	—
Commercial paper	2,699	—	2,699	—
Certificates of deposit	949	—	949	—
	$ 18,046	$ 12,836	$ 5,210	$ —
Liabilities:				
Derivative liabilities	$ —	$ —	$ —	$ —

	June 30, 2011			
	Total Carrying Value at June 30, 2011	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	(In thousands)			
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 December 31, 2011 and June 30, 2011, the fair values were derived by applying the following assumptions:

	December 31, 2011	June 30, 2011
Expected term (in years)	0.55	1.05
Stock volatility	90%	95%
Risk-free interest rate	0.07%	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 December 31,		Six Months Ended December 31,	
	2011	2010	2011	2010
	(In thousands)			
Balance at beginning of period	$ 128	$ 972	$ 170	$ 1,310
Change in fair value of derivative—other income	128	458	170	796
Balance at end of period	$ —	$ 514	$ —	$ 514

At December 31, 2011, the Company recorded a $14.8 million intangible asset impairment charge related to its Durasert and BioSilicon technologies (see Note 3). These fair value measurements were determined using a combination of market-based and income-based valuation methodologies, which incorporate unobservable inputs, thereby classifying the fair value as a level 3 measurement within the fair value hierarchy. The primary input used in the market-based approach was a 15% control premium that the Company estimated would be used by a market participant in valuing these assets. The primary inputs used in the income-based approach included after-tax weighted average cost of capital rates ranging from 10% to 20% that the Company estimated would be used by a market participant.

The following table summarizes the Company's assets carried at fair value measured on a nonrecurring basis at December 31, 2011 and the losses recorded during the period ended December 31, 2011:

	December 31, 2011				
	Total Carrying Value at December 31, 2011	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total Losses
	(In thousands)				
Finite-lived intangible assets	$ 4,596	$ —	$ —	$ 4,596	$14,830

6. Stockholders' Equity

Warrants to Purchase Common Shares

The following table provides a reconciliation of all US$ warrants for the six months ended December 31, 2011 and 2010:

	Six Months Ended December 31,			
	2011		2010	
	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	(2,814,701)	8.76	—	—
Balance and exercisable at end of period	4,800,047	$ 6.53	7,062,248	$ 7.53

At December 31, 2011, the remaining term of these outstanding warrants ranged from 0.4 to 4.1 years, representing a weighted average period of 10 months.

The following table provides a reconciliation of all A$ warrants for the six months ended December 31, 2011 and 2010:

	Six Months Ended December 31,			
	2011		2010	
	Number of Warrants	Weighted Average Exercise Price A$	Number of Warrants	Weighted Average Exercise Price A$
Balance at beginning of period	205,479	7.68	3,935,433	9.54
Expired	—	—	(716,538)	10.40
Balance and exercisable at end of period	205,479	7.68	3,218,895	9.35

At December 31, 2011, the remaining term of these outstanding warrants was 6.5 months. The weighted average exercise price of these warrants translated to US$ was $7.81 at December 31, 2011 and $9.51 at December 31, 2010. During the six months ended December 31, 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 six months ended December 31, 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	768,350	4.93		
Exercised	(53,950)	2.12		
Forfeited	(266,940)	4.05		
Outstanding at December 31, 2011	3,053,355	$ 3.10	7.94	$ —
Outstanding at December 31, 2011 - vested or unvested and expected to vest	2,968,696	$ 3.08	7.92	$ —
Exercisable at December 31, 2011	1,566,784	$ 2.44	7.33	$ —

Option grants for the six months ended December 31, 2011 consisted of 533,350 options with ratable annual vesting over 4 years, 100,000 options subject to performance and service conditions and 135,000 options to non-executive directors with 1-year cliff vesting. A total of 532,484 options vested during the six months ended December 31, 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 six months ended December 31, 2011 based on the following key assumptions:

Expected term (in years)	3.50 - 6.25
Stock volatility	88% -97%
Risk-free interest rate	0.53% -2.02%
Expected dividends	0%

The following table summarizes information about stock options for the six months ended December 31, 2011:

Weighted-average grant date fair value, per share	$ 2.41
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 six months ended December 31, 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 December 31, 2011	112,500	5.50	1.00	—

At December 31, 2011, translated into $, the weighted average exercise price of outstanding and exercisable options was $5.60.

Stock-Based Compensation Expense

The Company's statements of operations included total compensation expense from stock-based payment awards for the three and six months ended December 31, 2011 and 2010, as follows:

	Three Months Ended December 31,		Six Months Ended December 31,	
	2011	2010	2011	2010
	(In thousands)			
Compensation expense included in:				
Research and development	$ 122	$ 108	$ 269	$ 209
General and administrative	43	340	373	690
	$ 165	$ 448	$ 642	$ 899

Previously recorded compensation expense of $194,000 was reversed in the three months ended December 31, 2011 due to the forfeiture of performance-based options. Of that total, $162,000 was related to general and administrative and $32,000 was related to research and development. At December 31, 2011, there was approximately $1.9 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 $44,000 for the three months ended December 31, 2011 and $99,000 for the six months ended December 31, 2011, primarily related to earned foreign research and development tax credits.

For the six months ended December 31, 2011 and 2010, the Company had no significant unrecognized tax benefits in the accompanying unaudited condensed consolidated financial statements. At December 31, 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 and six month periods ended December 31, 2011 and 2010 as their inclusion would be anti-dilutive.

Potentially dilutive shares at December 31, 2011 and 2010 were as follows:

	December 31,	
	2011	2010
Options	3,165,855	2,854,730
Warrants	5,005,526	10,281,143
	8,171,381	13,135,873

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 diabetic macular edema ("DME") in the European Union (the "EU"); actions with respect to regulatory approval of ILUVIEN for DME in the U.S.; ability to obtain additional capital; ability to attain profitability; adverse side effects; exercise by Pfizer of the Latanoprost Product option; ability to complete clinical trials and obtain regulatory approval of product candidates; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; 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 guidelines, recommendations or studies; ability to protect intellectual property and avoid 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 stock price; possible dilution; possible influence by Pfizer; ability to 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.

Summary

The second quarter of fiscal 2012 was marked by the receipt by Alimera from the U.S. Food and Drug Administration (the "FDA") in November 2011 of a complete response letter ("CRL") in response to Alimera's resubmitted New Drug Application ("NDA") for ILUVIEN for DME rather than approval to market in the U.S.

- The 2011 CRL and subsequent drop in our market capitalization were impairment indicators with respect to our finite-lived intangible assets, with the recoverability assessment resulting in a $14.8 million impairment charge in the quarter.
- Because Alimera did not receive FDA approval of ILUVIEN for DME, we are not entitled to receive the $25.0 million milestone payment that would have been due on such approval and there will be no commercialization in the U.S., from which we would have been entitled to receive our share of any net profits. We have no committed funding from collaborative partners. We believe our capital resources at the end of the second quarter together with expected royalty income are sufficient to support our operations as currently conducted and planned into at least the beginning of calendar year 2013. We may seek to obtain additional capital resources and/or reduce our capital requirements as the result of possible approval and marketing of ILUVIEN for DME in the EU; possible new collaborative, licensing or other agreements; possible adjustments to our operating plan, including delaying initiation of clinical trials; and/or possible other agreements and transactions, which may include sales of assets or securities. There is no assurance that we will be successful in obtaining additional capital resources at all or on favorable terms or in reducing our capital requirements. See "*Liquidity and Capital Resources*" below.

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, our lead product candidate based on the Durasert technology, is currently under review by the Medicines and Healthcare products Regulatory Agency ("MHRA") in the United Kingdom and certain other regulatory authorities in the EU for the treatment of DME. 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 ("FAME™ Study") of ILUVIEN for the treatment of DME, a leading cause of vision loss for people under the age of 65.

On November 10, 2011, Alimera received a CRL from the FDA in response to the NDA for ILUVIEN for DME which Alimera resubmitted in May 2011. The resubmission followed the receipt of a CRL with respect to Alimera's original June 2010 NDA. The FDA stated in the 2011 CRL that it was unable to approve Alimera's NDA because it did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME. The FDA stated that the risks of adverse reactions shown for ILUVIEN in the FAME™ Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials. The FDA stated that Alimera will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. Alimera reported that it will be requesting a meeting with the FDA to clarify next steps.

In July 2010, utilizing the Decentralized Procedure, Alimera submitted a Marketing Authorization Application for ILUVIEN for DME to the MHRA in the United Kingdom and to regulatory authorities in six other EU countries. Alimera has reported that it expects a decision regarding the approval of ILUVIEN for DME in the first half of 2012.

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, depending on the availability of appropriate financing, we plan to advance this product candidate into pivotal multi-center Phase III trials and reference the NDA for ILUVIEN for DME (including clinical, nonclinical, 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, depending on the availability of appropriate financing, 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 technology 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, our second key technology system 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. Our BioSilicon technology is also designed to deliver smaller molecules.

Medidur™, Durasert™, BioSilicon™ and Tethadur™ are our trademarks. Retisert® and Vitrasert® are Bausch & Lomb's trademarks, and ILUVIEN® and FAME™ 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 December 31, 2011 Compared to Three Months Ended December 31, 2010:

	Three Months Ended December 31,		Change	
	2011	2010	Amounts	%
	(In thousands except percentages)			
Revenues	$ 630	$ 414	$ 216	52%
Operating expenses:				
Research and development	1,992	1,534	458	30%
General and administrative	1,451	2,001	(550)	(27)%
Impairment of intangible assets	14,830	—	14,830	na
Total operating expenses	18,273	3,535	14,738	417%
Loss from operations	(17,643)	(3,121)	(14,522)	(465)%
Other income (expense):				
Change in fair value of derivatives	128	458	(330)	(72)%
Interest income	11	6	5	83%
Other expense, net	—	(3)	3	100%
Total other income	139	461	(322)	(70)%
Loss before income taxes	(17,504)	(2,660)	(14,844)	(558)%
Income tax benefit (expense)	44	(35)	79	226%
Net loss	$(17,460)	$(2,695)	$(14,765)	(548)%

Revenues

Revenues increased by $216,000, or 52%, to $630,000 for the three months ended December 31, 2011 from $414,000 for the three months ended December 31, 2010, reflecting a $116,000 increase in collaborative research and development revenue primarily as a result of revenue recognized in connection with the June 2011 Restated Pfizer Agreement and a $100,000 increase in royalty income as a result of increased Retisert royalties from Bausch & Lomb.

Research and Development

Research and development increased by $458,000, or 30%, to $2.0 million for the three months ended December 31, 2011 from $1.5 million for the three months ended December 31, 2010, primarily attributable to increased personnel expense and the absence in the current year period of a $208,000 Federal grant award in the prior year quarter.

General and Administrative

General and administrative decreased by $550,000, or 27%, to $1.5 million for the three months ended December 31, 2011 from $2.0 million for the three months ended December 31, 2010, primarily attributable to reduced stock-based compensation expense, including reversal of stock-based compensation related to performance-based option forfeitures, and lower professional fees.

Impairment of Intangible Assets

Receipt of the 2011 CRL from the FDA and the significant decrease in our market capitalization at December 31, 2011 constituted impairment indicators of the Company's finite-lived intangible assets. The resulting recoverability assessment, using a combination of market-based and income-based valuation methodologies, derived an implied fair value of our intangible assets at December 31, 2011 of $4.6 million. Accordingly, we recorded a $14.8 million impairment charge with respect to our intangible assets.

Change in Fair Value of Derivatives

Income from the fair value of derivatives decreased by $330,000 to $128,000 for the three months ended December 31, 2011 from $458,000 for the three months ended December 31, 2010, primarily due to the expiration during fiscal year 2011 of approximately 3.7 million, or 95%, of the Company's outstanding A$-denominated warrants, partially offset by the significant reduction in the Company's share price during the current period.

Detachable warrants issued in share offerings denominated in A$ were recorded as derivative liabilities, subject to revaluation at each subsequent balance sheet date using the Black-Scholes valuation model, and changes in their fair values result in adjustments to our recorded derivative liabilities ($0 at December 31, 2011) and a corresponding income or expense in our statement of operations. Absent a significant increase in the Company's share price, we expect minimal changes in the fair values of these warrants through the last-to-expire of these warrants in July 2012.

Income Tax Benefit (Expense)

Income tax benefit of $44,000 for the three months ended December 31, 2011 compared to income tax expense of $35,000 for the three months ended December 31, 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 $29,000 net increase in foreign research and development tax credits.

Six Months Ended December 31, 2011 Compared to Six Months Ended December 31, 2010:

	Six Months Ended December 31,		Change	
	2011	2010	Amounts	%
	(In thousands except percentages)			
Revenues	$ 2,289	$ 890	$ 1,399	157%
Operating expenses:				
Research and development	4,121	3,276	845	26%
General and administrative	3,512	4,170	(658)	(16)%
Impairment of intangible assets	14,830	—	14,830	na
Total operating expenses	22,463	7,446	15,017	202%
Loss from operations	(20,174)	(6,556)	(13,618)	(208)%
Other income (expense):				
Change in fair value of derivatives	170	796	(626)	(79)%
Interest income	20	12	8	67%
Other expense, net	(2)	(11)	9	82%
Total other income	188	797	(609)	(76)%
Loss before income taxes	(19,986)	(5,759)	(14,227)	(247)%
Income tax benefit (expense)	99	(44)	143	325%
Net loss	$(19,887)	$(5,803)	$(14,084)	(243)%

Revenues

Revenues increased by $1.4 million, or 157%, to $2.3 million for the six months ended December 31, 2011 from $890,000 for the six months ended December 31, 2010, primarily as a result of recognition of deferred collaborative research and development revenues of $1.1 million due to the July 2011 termination of the Intrinsiq license and $470,000 in connection with the Restated Pfizer Agreement, partially offset by a $100,000 reduction in Retisert royalties from Bausch & Lomb.

Research and Development

Research and development increased by $845,000, or 26%, to $4.1 million for the six months ended December 31, 2011 from $3.3 million for the six months ended December 31, 2010. This increase was primarily attributable to increased personnel expense, costs of the latanoprost Phase I/II clinical trial under the Restated Pfizer Agreement and the absence in the current year of a $208,000 Federal grant award received in the prior year period.

General and Administrative

General and administrative decreased by $658,000, or 16%, to $3.5 million for the six months ended December 31, 2011 from $4.2 million for the six months ended December 31, 2010. This decrease was primarily attributable to reduced stock-based compensation expense, including reversal of stock-based compensation related to performance-based option forfeitures, and lower professional fees.

Impairment of Intangible Assets

The recoverability assessment of our intangible assets at December 31, 2011 described above resulted in the $14.8 million impairment charge recorded in the current year period.

Change in Fair Value of Derivatives

Income from the fair value of derivatives decreased by $626,000, or 79%, to $170,000 for the six months ended December 31, 2011 from $796,000 for the six months ended December 31, 2010, primarily due to the expiration of A$-denominated warrants during fiscal year 2011.

Income Tax Benefit (Expense)

Income tax benefit of $99,000 for the six months ended December 31, 2011 compared to income tax expense of $44,000 for the six months ended December 31, 2010. The net change was primarily attributable to (i) the absence in the current year period of $100,000 of U.S. federal alternative minimum tax expense in the prior year period and (ii) a $30,000 increase in foreign research and development tax credits.

Liquidity and Capital Resources

With the exception of fiscal 2010, we have incurred operating losses since our inception in 2000, including an $8.6 million loss in fiscal 2011, and our fiscal 2010 net income resulted from a one-time event. We expect to continue to generate negative cash flows from operations unless and until one or more of our product candidates achieves regulatory approval and sufficient revenues from commercialization. During the past three fiscal years, we financed our operations primarily from consideration received from our collaborative partners, including license fees, research and development funding and contingent note payments and from the proceeds of a January 2011 registered direct offering of our common stock and warrants. We currently have no committed funding from collaborative partners, and our cash, cash equivalents and marketable securities totaled $18.7 million at December 31, 2011. Because the FDA did not approve ILUVIEN for DME in November 2011, we are not entitled to receive the $25.0 million milestone payment that would have been due on such an approval, and Alimera will not be able to commercialize ILUVIEN for DME in the U.S. Although Alimera has applied to market ILUVIEN for DME in the U.K. and certain other EU countries, we do not know if it will receive such approval, and if it does, whether and when we will earn revenues from the commercialization of ILUVIEN for DME in the EU. We will receive funding under the Restated Pfizer Agreement only if Pfizer exercises its option with respect to the Latanoprost Product, and it becomes exercisable only upon completion of Phase II clinical trials, which have yet not been instituted, or after June 2012 if we cease development of the Latanoprost Product prior to completion of those trials. There is no assurance that Pfizer will exercise its option. Our royalty income from Bausch & Lomb is not expected to increase to a level sufficient to sustain our operations and may continue its historical downward trend. We believe that existing capital resources of $18.7 million at December 31, 2011 together with expected royalty income should enable us to maintain our current and planned operations into at least the beginning of calendar year 2013. We may also seek to obtain additional capital resources and/or reduce our capital requirements as the result of possible new collaborative, licensing or other agreements; adjustments to our operating plan, including delaying initiation of clinical trials; and/or possible other agreements and transactions, which may include sales of assets or securities.

Whether and when we will need, or desire, to take any of the actions described above will be influenced by the following factors, among others:

- whether and when we receive revenues from any commercialization of ILUVIEN for DME in the EU;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- whether and the extent to which we internally fund product development and programs, including clinical trials for the Latanoprost Product and the posterior uveitis insert, and ongoing research and development of BioSilicon;
- 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.

Many factors relating to us as well as to the economy generally, including the FDA's issuance to Alimera of the CRL in November 2011 with respect to ILUVIEN for DME, the status of approval and commercialization of ILUVIEN for DME in the EU, the status of development of our product candidates and the state of the economy and the financial and credit markets may make our ability to secure additional capital resources more difficult to obtain and on less favorable terms. If available, funding through collaboration, licensing or other agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products, additional equity financing may be dilutive to stockholders, and debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity. 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:

	Six Months Ended December 31,		
	2011	2010	Change
	(In thousands)		
Net loss:	$(19,887)	$(5,803)	$(14,084)
Changes in operating assets and liabilities	(2,303)	1,176	(3,479)
Other adjustments to reconcile net loss to cash flows from operating activities	17,170	1,825	15,345
Net cash used in operating activities	$ (5,020)	$(2,802)	$ (2,218)
Net cash provided by (used in) investing activities	$ 407	$(5,337)	$ 5,744
Net cash provided by financing activities	$ 114	$ —	$ 114

Net cash used in operating activities increased by $2.2 million to $5.0 million for the six months ended December 31, 2011 compared to $2.8 million for the six months ended December 31, 2010. The net increase of cash used in operating activities consisted of an aggregate $1.9 million decrease of collaborative research and development cash inflows principally from Pfizer and royalty cash inflows from Bausch & Lomb, and an approximate $300,000 increase in operating cash outflows, primarily related to higher personnel costs for research and development, partially offset by lower professional fees.

Net cash provided by investing activities consisted principally of $787,000 of maturities and sales, net of purchases, of marketable securities during the six months ended December 31, 2011 compared to $5.3 million of net purchases of marketable securities during the six months ended December 31, 2010. Purchases of property and equipment totaling $380,000 for the six months ended December 31, 2011 were primarily attributable to the July 2011 asset purchase agreement with Intrinsiq and leasehold improvements to our Malvern, U.K. laboratory and office space.

We had no borrowings or line of credit facilities as of December 31, 2011.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 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 December 31, 2011, the balance of our derivative liabilities, which relates to warrants denominated in A$, was $0 and was determined using the Black-Scholes valuation model. The change in fair value of derivatives resulted in income of $170,000 for the six months ended December 31, 2011 compared to $796,000 for the six months in the prior year.

During fiscal year 2011, approximately 3.7 million A$ warrants expired. At December 31, 2011, there were 205,479 warrants outstanding with a remaining contractual life of 6.5 months and a US$-equivalent exercise price of $7.81 per share compared to the $1.11 NASDAQ closing price of our common stock. Based on the significantly increased spread between the US$-equivalent exercise price of the warrants and our share price, the sensitivity of our consolidated statement of operations for the three months ended December 31, 2011 to assumed increases or decreases of our share price at December 31, 2011 is *de minimis*.

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 slight strengthening of the U.S. dollar during the three months ended December 31, 2011 compared to the prior year quarter resulted in a net decrease in research and development expenses of less than $10,000. 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 December 31, 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 $514,000 in stockholders' equity due to the translation of £1.3 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 December 31, 2011 in relation to the Pound Sterling, our stockholders' equity at December 31, 2011 would have decreased or increased, respectively, by $100,000.

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 December 31, 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 December 31, 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

RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

We have a history of losses and expect to continue to incur losses for the foreseeable future.

With the exception of fiscal 2010, we have incurred operating losses since our inception in 2000, including an $8.6 million loss in fiscal 2011, and our fiscal 2010 net income resulted from a one-time event. We do not currently have any assured sources of revenues. Because Alimera did not receive U.S. Food and Drug Administration approval of ILUVIEN for DME in November 2011, we are not entitled to receive the $25.0 million milestone payment that would have been due on such an approval and there will be no commercialization by Alimera in the U.S., from which we would have been entitled to receive our share of any net profits. Although Alimera has applied to market ILUVIEN for DME in the U.K. and certain other EU countries, we do not know if Alimera will receive such approval, and if it does, whether and when we will earn revenues from the commercialization of ILUVIEN for DME in the EU. We will receive funding under the Restated Pfizer Agreement only if Pfizer exercises its option with respect to the Latanoprost Product, which becomes exercisable only upon completion of Phase II clinical trials, which have yet not been instituted, or after June 2012 if we cease development of the Latanoprost Product prior to completion of those trials. There is no assurance that Pfizer will exercise its option. Our royalty income from Bausch & Lomb is not sufficient to offset our operating expense, is not expected to increase to a level sufficient to sustain our operations and may continue its historical downward trend. Our ability to achieve profitability is expected to depend upon our or our licensees' ability to achieve regulatory approval and sufficient revenues from commercialization of one or more of our product candidates.

We expect to need additional capital resources to fund our operations, and our ability to obtain them is uncertain.

We expect to continue to generate negative cash flows from operations unless and until one or more of our product candidates achieves regulatory approval and sufficient revenues from commercialization. During the past three fiscal years, we have financed our operations primarily from consideration received from our collaborative partners, including license fees, research and development funding and contingent note payments and from the proceeds of a January 2011 registered direct offering of our common stock and warrants. We currently have no committed funding from collaborative partners, and our cash, cash equivalents and marketable securities, totaled $18.7 million at December 31, 2011. We believe that these capital resources together with expected royalty income from Bausch & Lomb should enable us to maintain our current and planned operations into at least the beginning of calendar year 2013. Our capital resources could be enhanced if Alimera receives approval for and successfully markets or sublicenses the commercialization of ILUVIEN for DME in the EU, although even so, the amount and time frame for our receipt of any revenues from such activities would be uncertain. We may also seek to obtain additional capital resources and/or reduce our capital requirements as the result of possible new collaborative, licensing or other agreements; possible adjustments to our operating plan, including delaying initiation of clinical trials; and/or possible other agreements and transactions, which may include sales of assets or securities. Whether and when we will need, or desire, to take any of the actions described above will be influenced by the following factors, among others:

- whether and when we receive revenues from any commercialization of ILUVIEN for DME in the EU;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- whether and the extent to which we internally fund product development and programs, including clinical trials for the Latanoprost Product and the posterior uveitis insert and ongoing research and development of BioSilicon;
- 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.

Many factors relating to us as well as to the economy generally, including the FDA's issuance to Alimera of the 2011 CRL with respect to ILUVIEN for DME, the status of approval and commercialization of ILUVIEN for DME in the EU, the status of development of our product candidates and the state of the economy and the financial and credit markets may make our ability to secure additional capital resources more difficult to obtain and on less favorable terms. If available, funding through collaboration, licensing or other agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products, additional equity financing may be dilutive to stockholders, and debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity. 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.

If the recorded value of our intangible assets under GAAP is further impaired, our financial results could be adversely affected, which could adversely affect the price of our securities.

We recorded significant amounts of intangible assets in connection with earlier acquisitions. We took impairment charges of $3.1 million with respect to the value of our Durasert intangible asset and $11.7 million with respect to the value of our BioSilicon intangible asset as of December 31, 2011. Previously, we had taken a $60.1 million impairment charge on the carrying value of our goodwill as of June 30, 2008 (which reduced the balance to zero) and a $45.3 million impairment charge on the recorded value of our Durasert intangible asset as of June 30, 2007. We have $4.6 million of intangible assets on our balance sheet as of December 31, 2011, of which $3.2 million relates to our Durasert technology and $1.4 million relates to our BioSilicon technology. We will continue to conduct impairment analyses of our intangible assets as required, and we would be required to take additional impairment charges in the future if any recoverability assessment of those assets reflect implied fair market values which are less than our recorded value, and such charges could be significant. The carrying values of our Durasert and BioSilicon technology systems could be impaired as a result of various factors, including, without limitation, adverse events with respect to the status of clinical development, regulatory approval and success of commercialization of products using those technologies, such as approval of ILUVIEN for DME in the EU and timely advancement of the Latanoprost Product utilizing the BioSilicon and Durasert technologies into more advanced clinical trials, and significant changes in our market capitalization. Further impairment charges on our intangible assets could have a material adverse effect on our results of operations, which could, in turn, adversely affect the price of our securities.

Our operating results may fluctuate significantly from period to period.

Our operating results have fluctuated significantly from period to period in the past and may continue to do so in the future due to many factors, including:

- timing, receipt, amount and revenue recognition of payments, if any, from collaboration partners, including, without limitation, collaborative research and development, milestone, royalty and other payments;
- execution, amendment and termination of collaboration agreements;
- scope, duration and success of collaboration agreements;
- amount of internally funded research and development costs, including pre-clinical studies and clinical trials;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- changes in accounting estimates, policies or principles and intangible asset impairments.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors in the financial community, which may result in further decreases in our stock price.

Our royalty income from Bausch & Lomb may continue to decline.

The annual trend of the royalties from Bausch & Lomb for Retisert (including the historical amounts previously retained by Bausch & Lomb) and Vitrasert has generally declined and may continue to do so. There is no assurance that Bausch & Lomb will continue to market either or both of these products. We do not expect that our royalty income from Bausch & Lomb for these products will ever become a material source of revenue for us.

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

Alimera has not obtained FDA regulatory approval for ILUVIEN for DME, our lead product candidate, and there is no assurance that Alimera will be able to do so, which prevents commercialization in the U.S. and our receipt of revenues from such commercialization and materially impairs our financial prospects.

Alimera received a CRL from the FDA with respect to its NDA for ILUVIEN for DME in December 2010 which included 24 month data from the FAME Study and the 2011 CRL in response to the resubmitted NDA which included 36 month data. In the 2011 CRL, the FDA stated that it was unable to approve the NDA because it did not provide sufficient data to support that ILUVIEN is safe and effective in the treatment of patients with DME, that the risks of adverse reactions shown for ILUVIEN in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN in these clinical trials and that Alimera will need to conduct two additional clinical trials to demonstrate that the product is safe and effective for the proposed indication. While Alimera reported that it will be requesting a meeting with the FDA to clarify next steps, there can be no assurance that Alimera's meeting with the FDA will provide any new or different information than the 2011 CRL. Additional clinical trials are very expensive, Alimera may not commence or complete any additional clinical trials or even if it does so, there is no assurance that they would produce different results sufficient to demonstrate to the FDA that ILUVIEN for DME is safe and effective. Accordingly, ILUVIEN for DME may never be approved and marketed in the U.S. and we will not receive any payments to which we would be entitled on approval and commercialization, which is materially adverse to our business. Further, we do not know whether Alimera will continue to seek to develop, or receive approval from the FDA or other regulatory agencies for, ILUVIEN for the treatment of other eye conditions currently being studied under Alimera's agreement with us.

Approval of ILUVIEN for DME in the EU is uncertain, and even if approved, we do not know what revenues, if any, we will receive from any commercialization of ILUVIEN for DME in the EU.

In July 2010, Alimera submitted a Marketing Authorization Application for ILUVIEN for DME to the MHRA in the United Kingdom and to the regulatory authorities in six other EU countries under the Decentralized Procedure, and if approved, may seek marketing authorization from additional EU countries through the Mutual Recognition Procedure. Alimera has reported that it expects a decision regarding the approval of ILUVIEN for DME in the first half of 2012. There is no assurance that Alimera will receive marketing approval for ILUVIEN for DME in the seven EU countries under the Decentralized Procedure or in any additional EU countries to which it may apply under the Mutual Recognition Procedure and, accordingly, that ILUVIEN for DME will be marketed in the EU or that we will receive any revenues from the commercialization of ILUVIEN for DME in the EU. Alimera previously stated that it intends to seek a commercialization partner for sales and marketing activities outside North America. If Alimera receives marketing approval for ILUVIEN for DME in the EU, we do not know if Alimera will seek such a partner or be successful in doing so or will seek to commercialize the product itself. Under our agreement with Alimera, we are entitled to 20% of net profits, as defined, on sales of ILUVIEN by Alimera, subject to an offset of 20% of pre-profitability commercialization costs, as defined, incurred by Alimera, while in the event Alimera sublicenses commercialization, we are entitled to receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. Prices of drugs in the EU are regulated and are generally lower than those in the United States, which could affect the amount of any revenues from the commercialization of ILUVIEN for DME in the EU.

ILUVIEN and our insert for posterior uveitis deliver FAc, a corticosteroid that has demonstrated undesirable side effects in the eye, which at least in part resulted in the 2011 CRL for ILUVIEN for DME and may affect the approvability and success of ILUVIEN for other eye diseases and of our posterior uveitis insert of the same design.

Both ILUVIEN and our insert for posterior uveitis of the same design deliver the corticosteroid FAc, which is associated with undesirable side effects in the eye such as cataract formation and elevated

intraocular pressure which may increase the risk of glaucoma. In the 2011 CRL, the FDA stated that the risks of adverse reactions shown for ILUVIEN for DME in the FAME Study were significant and were not offset by the benefits demonstrated by ILUVIEN for DME in these clinical trials. There is no assurance that ILUVIEN for DME will be approved by the MHRA and other EU regulators. These side effects may affect the approvability of ILUVIEN for the other eye conditions for which it is being studied, and even if approved, these side effects may adversely affect the successful marketing of ILUVIEN for DME in the EU. We do not know whether our insert for the treatment of posterior uveitis of the same design as ILUVIEN, which also delivers FAc, will be able to demonstrate that it is safe and efficacious for the treatment of posterior uveitis in light of its side effects from FAc.

There is no assurance that Pfizer will exercise its option with respect to the Latanoprost Product or that we will receive any further revenues under the Restated Pfizer Agreement.

In June 2011, we amended our Collaborative Research and License Agreement with Pfizer to focus solely on the development of the Lantanoprost Product. Development of this product through Phase II clinical trials is at our own expense. Pfizer has an option for an exclusive, worldwide license to develop and commercialize the Latanoprost Product upon our completion of Phase II clinical trials or after June 2012 if we cease development of the Lantanoprost Product prior to completion of those trials. There is no assurance that we will complete the Phase II clinical trials for the Latanoprost Product, that if completed, the trials will be successful, that Pfizer will, in any event, exercise its option or that if exercised, the Lantanoprost Product will achieve successful Phase III trial results, regulatory approvals or commercial success. As a result, there is no assurance that we will receive any further licensing, milestone or royalty payments under the Restated Pfizer Agreement.

If we or our licensees are unable to or do not complete clinical trials for our product candidates or do not receive the necessary regulatory approvals, we or our licensees will be unable to commercialize our product candidates.

Our current and future activities are and will be subject to stringent regulation by governmental authorities both in the United States and in any other country in which our products are marketed. Before we or our licensees can manufacture, market and sell any of our product candidates, approval from the FDA and/or foreign regulatory authorities is required to market in the applicable jurisdictions. Generally, in order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that a product candidate is safe for human use and effective for its targeted disease or condition.

Other than ILUVIEN for DME, none of our product candidates have completed or are in pivotal clinical trials. An investigator-sponsored Phase I/II study of the Lantanoprost Product is ongoing but we have not commenced Phase II clinical trials, an investigator-sponsored Phase I/II study of the posterior uveitis implant has been opened but we have not commenced pivotal trials, and we have no ongoing pre-clinical or clinical studies with respect to BioSilicon product candidates. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or to approved products. There is no assurance that we or licensees will commence or continue clinical trials for any of our product candidates. If clinical trials conducted by or for us or our licensees for any of our product candidates do not provide the necessary evidence of safety and efficacy, those product candidates cannot not be manufactured and sold, and will not generate revenues. Initial or subsequent clinical trials may not be initiated by or for us or our licensees for product candidates or may be delayed or fail due to many factors, including the following:

- our (or our licensees') lack of sufficient funding to pursue trials rapidly or at all;
- our (or our licensees') inability to attract clinical investigators for trials;
- our (or our licensees') inability to recruit patients in sufficient numbers or at the expected rate;
- our inability to find or reach agreement with licensees to undertake clinical trials;
- decisions by licensees not to exercise options for products and not to pursue products licensed to them;
- adverse side effects;
- failure of trials to demonstrate a product candidate's safety and efficacy;
- our (or our licensees') failure to meet FDA or other regulatory agency requirements for clinical trial design or inadequate clinical trial design;
- our (or our licensees') inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;

- failures by, changes in our (or our licensees') relationship with, or other issues at contract research organizations, third-party vendors and investigators responsible for pre-clinical testing and clinical trials;
- our (or our licensees') inability to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with materials;
- failure to comply with current good manufacturing practices ("cGMP") or similar foreign regulatory requirements or other manufacturing issues;
- requests by regulatory authorities for additional data or clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differs from our (or our licensees') interpretations or conclusions that product candidates meet quality standards for stability, quality, purity and potency;
- governmental or regulatory delays, or changes in approval policies or regulations; and
- developments, clinical trial results and other factors with respect to competitive products and treatments.

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

The FDA or other relevant regulatory agencies may not approve our product candidates for manufacture and sale, and any approval by the FDA does not ensure approval by other regulatory agencies or vice versa (which could require us to comply with numerous and varying regulatory requirements, possibly including additional clinical testing). Any product approvals we or our licensees achieve could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the products' marketing approval. In either case, marketing efforts with respect to the affected product would have to cease. In addition, the FDA or other regulatory agencies may impose limitations on the indicated uses for which a product may be marketed, which may reduce the size of or otherwise limit the potential market for the product.

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

We have a limited ability to develop and market products ourselves. If we are unable to find development or marketing partners, or our development or marketing partners do not successfully develop or market our products, we may be unable to effectively develop and market products on our own.

We have limited product development capability and no marketing or sales staff. Developing products and achieving market acceptance for them can require extensive and substantial efforts by experienced personnel as well as expenditure of significant funds. We may not be able to establish sufficient capabilities necessary to develop products and achieve market penetration ourselves.

Our business strategy includes entering into collaborative and licensing arrangements for the development and commercialization of our product candidates, and we currently have collaboration and licensing arrangements with Alimera, Pfizer and Bausch & Lomb. The curtailment or termination of any of these arrangements could adversely affect our business, our ability to develop and commercialize our products, product candidates and proposed products and our ability to fund operations.

The success of these and future collaborative and licensing arrangements will depend heavily on the experience, resources, efforts and activities of our licensees. Our licensees have, and are expected to have, significant discretion in making decisions related to the development of product candidates and the

commercialization of products under these collaboration agreements. Risks that we face in connection with our collaboration and licensing strategy include the following:

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;
- we are required, and expect to be required, under our collaborative and licensing arrangements not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees, consistent with other pharmaceutical and biotechnology companies that have historically acted similarly, may for a variety of reasons change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

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

Our current licensees may terminate their agreements with us at any time, and if they do, we will lose the benefits of those agreements and may not be able to develop and sell products currently licensed to them.

Our licensees have rights of termination under our agreements with them. Exercise of termination rights by one or more of our licensees may leave us without the financial benefits and development, marketing or sales resources provided under the terminated agreement, which may have an adverse effect on our business, financial condition and results of operations. Additionally, our interests may not continue to coincide with those of our partners, and our partners may develop, independently or with third parties, products or technologies that could compete with our products. Further, we may disagree with our partners over the rights and obligations under those agreements, including ownership of technologies or other proprietary interests, noncompetition, payments or other issues, which could result in breach of the agreements including related damages or injunctive relief or termination.

Pfizer may terminate the Restated Pfizer Agreement with respect to the Lantanoprost Product without penalty at any time and for any reason upon 60 days' written notice. We have exclusively licensed our technology underlying Vitrasert and Retisert to Bausch & Lomb, which can terminate its agreement with us without penalty at any time upon 90 days' written notice. We have licensed the technology underlying ILUVIEN for DME and certain ophthalmic applications to Alimera. Alimera has financial responsibility for the development of ILUVIEN and any other licensed products developed under our collaboration agreement, along with sole responsibility for the commercialization of such licensed products. Alimera may abandon the development and commercialization of any licensed product at any time.

Any of Pfizer, Alimera or Bausch & Lomb may decide not to continue to develop, exercise options or commercialize any or all of the licensed products under their respective agreements, change strategic focus, pursue alternative technologies or develop competing products. While Pfizer and Bausch & Lomb have significant experience in the ophthalmic field and have substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to our technologies. Alimera has limited experience and limited financial resources, and if ILUVIEN for DME is approved in the EU, it would be Alimera's first product. Because we do not currently have sufficient funding or internal capabilities to develop and commercialize our products and product candidates, decisions, actions, breach or termination of these agreements by Pfizer, Bausch & Lomb or Alimera could delay or stop the development or commercialization of any of the products or product candidates licensed to such entities.

If our competitors and potential competitors develop products that receive regulatory approval before our product candidates are approved or reach the market prior to our product candidates, are more effective, or have fewer side effects than our products or product candidates or are more effectively marketed or cost less, our products or product candidates may not be approved, may not achieve the sales we anticipate and could be rendered obsolete.

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For many of our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development ranging from discovery to advanced clinical trials. For example, Lucentis® has been approved to treat patients with DME in the EU and Bayer and Regeneron instituted Phase 3 studies of EYLEA®, already approved in the U.S. and E.U. to treat wet age-related macular degeneration, to treat DME. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may cure our targeted diseases or their underlying causes completely, which could result in our product candidates not being approved, reduce demand for our products and product candidates or render them noncompetitive or obsolete. For example, sales of Vitrasert for the treatment of CMV retinitis, a disease that affects people with late-stage AIDS, declined significantly because of treatments that delay the onset of late-stage AIDS.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than us. Our competitors may succeed in developing alternate technologies and products that, in comparison to the products we have and are seeking to develop:

- are more effective and easier to use;
- are more economical;
- have fewer side effects; or
- may otherwise render our products less competitive or obsolete.

Many of these competitors have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances and manufacturing and marketing products.

Our products and product candidates may not achieve and maintain market acceptance, and may never generate significant revenues.

In both domestic and foreign markets, the commercial success of our products and product candidates will require not only obtaining regulatory approvals but also obtaining market acceptance by retinal specialists and other doctors, patients, government health administration authorities and other third-party payors. Whether and to what extent our products and product candidates achieve and maintain market acceptance will depend on a number of factors, including demonstrated safety and efficacy, cost-effectiveness, potential advantages over other therapies, our and our collaborative partners' marketing and distribution efforts and the reimbursement policies of government and other third-party payors. In particular, if government and other third-party payors do not provide adequate coverage and reimbursement levels for our products and product candidates, the market acceptance of our products and product candidates will be limited. Both government and other third-party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they might challenge the price and cost-effectiveness of our products, or refuse to provide coverage for uses of our products for certain disease indications. If our products and product candidates fail to achieve and maintain market acceptance, they may fail to generate significant revenues and our business may be significantly harmed.

Guidelines, recommendations and studies published by various organizations could reduce the use of our products and product candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies related to our products and product candidates or our competitors' products. Any such guidelines, recommendations or studies that reflect negatively on our products or product candidates could result in decreased use, sales of, and revenues from, one or more of our products and product candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our products and product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We rely heavily upon patents and trade secrets to protect our proprietary technologies. If we fail to protect our intellectual property or infringe on others' technologies, our ability to develop and market our products and product candidates may be compromised.

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of December 31, 2011, we had 189 patents and 176 pending patent applications, including patents and pending applications covering our Durasert, BioSilicon and CODRUG technologies. Intellectual property protection of our technologies is uncertain. We expect to seek to patent and protect our proprietary technologies. However, there is no assurance that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. In addition, we may not have sufficient funds to patent and protect our proprietary technologies to the extent that we would desire, or at all. If we were determined to be infringing any third party patent, we could be required to pay damages, alter our products or processes, obtain licenses, pay royalties or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. In addition, many foreign country laws may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in the United States and Patent Co-operation Treaty countries.

Prior art may reduce the scope or protection of, or invalidate, our patents. Previously conducted research or published discoveries may prevent our patents from being granted, invalidate issued patents or narrow the scope of any protection obtained. Reduction in scope of protection or invalidation of our licensed or owned patents, or our inability to obtain patents, may enable other companies to develop products that compete with our products and product candidates on the basis of the same or similar technology. As a result, our patents and those of our licensors may not provide any or sufficient protection against competitors. While we have not been, and are not currently involved in, any litigation over intellectual property, such litigation may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. We may also be sued by one or more third parties alleging that we infringe their intellectual property rights. Any intellectual property litigation would be likely to result in substantial costs to us and diversion of our efforts, and could prevent or delay our discovery or development of product candidates. If our competitors claim technology also claimed by us, and if they prepare and file patent applications in the U.S. or other jurisdictions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or the appropriate foreign patent office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties and/or requiring us to cease using certain technologies.

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

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

If we fail to retain key personnel, our business could suffer.

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

If we are subject to product liability suits, we may not have sufficient insurance to cover damages.

The testing, manufacturing, and marketing and sale of the products utilizing our technologies involve risks that product liability claims may be asserted against us and/or our licensees. Our current clinical trial and product

liability insurance may not be adequate to cover damages resulting from product liability claims. Regardless of their merit or eventual outcome, product liability claims could require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our products and product candidates or result in reputational harm and could result in the payment of a significant damage award. Our product liability insurance coverage is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to acquire sufficient clinical trial or product liability insurance in the future on reasonable commercial terms, if at all.

The trend towards consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There is an ongoing trend of consolidation in the pharmaceutical and biotechnology industries. This consolidation trend could result in the remaining companies having greater financial resources and technological capabilities, thus intensifying competition. This trend could also result in fewer potential collaboration partners or licensees for our product candidates. In addition, if a consolidating company is already doing business with our competitors, we could lose existing or potential future licensees or collaboration partners as a result of such consolidation.

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

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

If we or our licensees encounter problems with product manufacturing, there could be delays in product development or commercialization, which would adversely affect our future profitability.

Our ability and that of our licensees to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, develop and commercialize our product candidates will depend, in part, upon our and our licensees' ability to manufacture our products and product candidates, either directly or through third parties, in accordance with FDA and other regulatory requirements. The manufacture, packaging and testing of our products and product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with applicable cGMP and comparable foreign requirements. Any change in a manufacturing process or procedure used for one of our products or product candidates, including a change in the location at which a product or product candidate is being manufactured or in the third-party manufacturer being used, may require the FDA's and similar foreign regulatory entities' prior review and/or approval in accordance with applicable cGMP or other regulations. Additionally, the FDA and similar foreign regulatory entities may implement new standards, or change their interpretation and enforcement of existing standards, for the manufacture, packaging and testing of products at any time.

There are a limited number of manufacturers that operate under cGMP and other foreign regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Alimera has contracted with third-party manufacturers with respect to the manufacture of components of ILUVIEN. Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions. In addition, we or our collaborative partners may not be able to manufacture our product candidates successfully or have a third party manufacture them in a cost-effective manner. If we or our collaborative partners are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products.

We manufacture supplies in connection with pre-clinical or clinical studies conducted by us or our collaboration partners. Under our collaboration agreements with Alimera, Pfizer and Bausch & Lomb, we have provided our licensees the exclusive rights to manufacture commercial quantities of products, once approved for marketing. Our and our licensees' reliance on third-party manufacturers entails risks, including:

- failure of third parties to comply with cGMP and other applicable US and foreign regulations and to employ adequate quality assurance practices;

- inability to obtain the materials necessary to produce a product or to formulate the active pharmaceutical ingredient on commercially reasonable terms, if at all;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our or our licensees' control;
- termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or difficult; and
- inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

Problems associated with international business operations could affect our ability to manufacture and sell our products. If we encounter such problems, our costs could increase and our development of products could be delayed.

We currently maintain offices and research and development facilities in the U.S. and the U.K., and our goal is to develop products for sale by us and our licensees in most major world healthcare markets. Manufacturing of pharmaceutical products requires us or our licensees to comply with regulations regarding safety and quality and to obtain country and jurisdiction-specific regulatory approvals and clearances. We or our licensees may not be able to comply with such regulations or to obtain or maintain needed regulatory approvals and clearances or may be required to incur significant costs in doing so. In addition, our operations and future revenues may be subject to a number of risks associated with foreign commerce, including the following:

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

Credit and financial market conditions may exacerbate certain risks affecting our business.

Sales of our products are, and if approved, our product candidates will, depend on the availability and extent of reimbursement from government and other third-party payors. Difficult credit and financial market conditions may increase the risk that government and other third-party payors will reduce the availability or extent of reimbursement for our products, and the risk that third-party payors will delay or default on reimbursement obligations.

Development and sales of our products and product candidates also heavily depend on collaborative partners and third-party suppliers. Difficult credit and financial market conditions may increase the risk that there are delays, disruptions or defaults in the performance of these third parties' obligations to us.

Legislative or regulatory changes may adversely affect our business, operations and financial results.

Our industry is highly regulated and new laws, regulations and judicial decisions, and new interpretations of existing laws, regulations and judicial decisions, may adversely affect our business, operations and financial results.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the "PPACA"), is intended to expand U.S. healthcare coverage primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of this new law could significantly reduce payments from Medicare and Medicaid for our products and product candidates over the next 10 years, resulting in potentially significant reductions of our revenues. The PPACA's effects cannot be fully known until its provisions are implemented, and the Centers for Medicare & Medicaid Services, and other federal and state agencies, issue applicable regulations or guidance. Proposed U.S. state healthcare reforms, and any foreign healthcare reforms, also could alter the availability, methods and rates of reimbursements from the government and other third-party payors for our products and product candidates, and could adversely affect our business strategy, operations and financial results.

The Food and Drug Administration Amendments Act of 2007 granted the FDA enhanced authority over products already approved for sale, including authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this relatively new authority could result in delays and increased costs during product development, clinical trials and regulatory review and approval, increased costs following regulatory approval to assure compliance with new post-approval regulatory requirements, and potential restrictions on the sale or distribution of approved products following regulatory approval.

RISKS RELATED TO OUR COMMON STOCK

The price of our common stock may be volatile.

The price of our common stock (including common stock represented by CHESS Depositary Interests (CDIs)) may be affected by developments directly affecting our business as well as by developments out of our control or not specific to us. The price of our common stock dropped significantly when the FDA issued its 2011 CRL with respect to ILUVIEN for DME. The biotechnology sector, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volume of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock (and CDIs) and their trading volumes may fluctuate based on a number of factors including, but not limited to:

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

In addition, low trading volume in our common stock or our CDIs may increase their price volatility. Holders of our common stock and CDIs may not be able to liquidate their positions at the desired time or price. Finally, we will need to continue to meet the listing requirements of the NASDAQ Global Market including the minimum stock price for our stock to continue to be traded on that exchange.

If the holders of our outstanding warrants and stock options exercise their warrants and options, ownership of our common stock holders may be diluted, and our stock price may decline.

As of December 31, 2011, we had outstanding approximately 5.0 million investor warrants and 3.2 million employee and director options to acquire shares of our common stock, or approximately 28.2% of our shares on a fully diluted basis. Although the exercise prices of the substantial majority of the warrants and stock options were significantly above the market price at that date, the issuance of shares of our common stock upon exercise of our outstanding warrants and stock options could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price. The overhang of outstanding warrants and options may adversely affect our stock price. The warrant exercise prices may be adjusted under certain circumstances.

Pfizer owns a significant percentage of our common stock and is a collaborative partner and therefore may be able to influence our business in ways that are not beneficial to you.

Pfizer owned approximately 9.0% of our outstanding shares as of December 31, 2011 and is a collaborative partner. As a result, Pfizer may be able to exert significant influence over our board of directors and how we operate our business. The concentration of ownership may also have the effect of delaying or preventing a change in control of our company.

We have paid penalties pursuant to registration agreements with securities holders relating to resale registration statements, and any requirement to pay such penalties in the future may have a material adverse effect on our financial condition.

We have registration rights agreements that require us to file and maintain the effectiveness of registration statements for the resale of our common stock, which provide for monetary penalties in the event of our failure to do so. During the year ended June 30, 2007, we paid registration delay penalties of approximately $2.3 million in connection with then outstanding convertible notes. Our failure or inability to maintain the effectiveness of any of our required registration statements or to adequately update information in the related prospectuses may subject us to additional penalties under our current registration rights agreements. Payment of additional penalties may have a material adverse effect on our financial condition and may require us to suspend, curtail or terminate our operations or delay, reduce the scope of or eliminate one or more of our research and development programs, any of which could have a material adverse effect on our business.

We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no cash dividends on our common shares have been declared or paid by us and we have no intention of paying any such dividends in the foreseeable future.

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 December 31, 2011, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statement of Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements

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SIGNATURES

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

pSivida Corp.

Date: February 9, 2012

By: /s/ Paul Ashton
Name: Paul Ashton
Title: President and Chief Executive Officer

Exhibit 31.1

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: February 9, 2012

/s/ Paul Ashton

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

Exhibit 31.2

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: February 9, 2012

/s/ Leonard S. Ross

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

Exhibit 32.1

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 December 31, 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: February 9, 2012

/s/ Paul Ashton

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

Exhibit 32.2

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 December 31, 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: February 9, 2012

/s/ Leonard S. Ross

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