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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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

For the quarterly period ended December 31, 2010

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

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**pSivida Corp.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**02472**  
(Zip Code)

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

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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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

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 20,741,392 shares of the registrant's common stock, \$0.001 par value, outstanding as of February 7, 2011.

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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, 2010	June 30, 2010
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 7,377	\$ 15,514
Marketable securities	7,266	2,051
Accounts and other receivables	1,094	1,111
Prepaid expenses and other current assets	121	358
Total current assets	15,858	19,034
Property and equipment, net	88	43
Intangible assets, net	22,681	23,877
Other assets	61	60
<b>Total assets</b>	<b>\$ 38,688</b>	<b>\$ 43,014</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 219	\$ 387
Accrued expenses	803	1,158
Deferred revenue	81	79
Derivative liabilities	514	1,310
Total current liabilities	1,617	2,934
Deferred revenue	8,305	6,817
Deferred tax liabilities	222	222
<b>Total liabilities</b>	<b>10,144</b>	<b>9,973</b>
<b>Stockholders' equity:</b>		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$.001 par value, 60,000,000 shares authorized, 18,531,392 shares issued and outstanding at December 31, 2010 and June 30, 2010, respectively	19	19
Additional paid-in capital	251,695	250,796
Accumulated deficit	(224,098)	(218,295)
Accumulated other comprehensive income	928	521
Total stockholders' equity	28,544	33,041
<b>Total liabilities and stockholders' equity</b>	<b>\$ 38,688</b>	<b>\$ 43,014</b>

See notes to condensed consolidated financial statements

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

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Six Months Ended</u> <u>December 31,</u>	
	<u>2010</u>	<u>2009</u>	<u>2010</u>	<u>2009</u>
<b>Revenues:</b>				
Collaborative research and development	\$ 88	\$ 3,406	\$ 162	\$ 6,752
Royalty income	326	27	728	64
Total revenues	<u>414</u>	<u>3,433</u>	<u>890</u>	<u>6,816</u>
<b>Operating expenses:</b>				
Research and development	1,534	1,728	3,276	3,528
General and administrative	2,001	1,818	4,170	3,508
Total operating expenses	<u>3,535</u>	<u>3,546</u>	<u>7,446</u>	<u>7,036</u>
Loss from operations	<u>(3,121)</u>	<u>(113)</u>	<u>(6,556)</u>	<u>(220)</u>
<b>Other income (expense):</b>				
Change in fair value of derivatives	458	83	796	(1,436)
Interest income	6	—	12	2
Other (expense) income, net	<u>(3)</u>	<u>(4)</u>	<u>(11)</u>	<u>5</u>
Total other income (expense)	<u>461</u>	<u>79</u>	<u>797</u>	<u>(1,429)</u>
Loss before income taxes	<u>(2,660)</u>	<u>(34)</u>	<u>(5,759)</u>	<u>(1,649)</u>
Income tax (expense) benefit	<u>(35)</u>	<u>10</u>	<u>(44)</u>	<u>34</u>
Net loss	<u>\$ (2,695)</u>	<u>\$ (24)</u>	<u>\$ (5,803)</u>	<u>\$ (1,615)</u>
Basic and diluted net loss per share:	<u>\$ (0.15)</u>	<u>\$ —</u>	<u>\$ (0.31)</u>	<u>\$ (0.09)</u>
<b>Weighted average common shares outstanding:</b>				
Basic and diluted	<u>18,531</u>	<u>18,317</u>	<u>18,531</u>	<u>18,305</u>

See notes to condensed consolidated financial statements

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

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Total Stockholders' Equity</u>
	<u>Number of Shares</u>	<u>Par Value Amount</u>				
Balance at July 1, 2010	18,531,392	\$ 19	\$250,796	\$ (218,295)	\$ 521	\$ 33,041
Comprehensive loss:						
Net loss	—	—	—	(5,803)	—	(5,803)
Foreign currency translation adjustments	—	—	—	—	402	402
Net unrealized gain on marketable securities	—	—	—	—	5	5
Total comprehensive loss						\$ (5,396)
Stock-based compensation	—	—	899	—	—	899
Balance at December 31, 2010	<u>18,531,392</u>	<u>\$ 19</u>	<u>\$251,695</u>	<u>\$ (224,098)</u>	<u>\$ 928</u>	<u>\$ 28,544</u>

See notes to condensed consolidated financial statements

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

	<b>Six Months Ended</b>	
	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (5,803)	\$(1,615)
Adjustments to reconcile net loss to cash flows from operating activities:		
Amortization of intangible assets	1,633	1,684
Depreciation of property and equipment	23	19
Change in fair value of derivatives	(796)	1,436
Stock-based compensation expense	899	713
Amortization of bond premium on marketable securities	66	—
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	263	301
Accounts payable and accrued expenses	(546)	(337)
Deferred revenue	1,459	(4,449)
Net cash used in operating activities	<u>(2,802)</u>	<u>(2,248)</u>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(6,028)	—
Maturities of marketable securities	750	—
Purchases of property and equipment	(59)	—
Net cash used in investing activities	<u>(5,337)</u>	<u>—</u>
<b>Cash flows from financing activities:</b>		
Exercise of warrants	—	484
Net cash provided by financing activities	<u>—</u>	<u>484</u>
Effect of foreign exchange rate changes on cash and cash equivalents	2	(6)
<b>Net decrease in cash and cash equivalents</b>	<b>(8,137)</b>	<b>(1,770)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>15,514</b>	<b>6,899</b>
<b>Cash and cash equivalents at end of period</b>	<b><u>\$ 7,377</u></b>	<b><u>\$ 5,129</u></b>

See notes to condensed consolidated financial statements

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

**1. Operations and Basis of Presentation**

The accompanying condensed consolidated financial statements of pSivida Corp. and subsidiaries (the “Company”) for the three and six months ended December 31, 2010 and 2009 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, 2010. 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, 2010, 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, 2010 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 that are administered by implantation, injection or insertion. Once administered, a drug is released on a controlled and level basis for months or years. The Company has two core technology systems, Durasert™ and BioSilicon™. Utilizing three generations of its Durasert technology system, the Company has one product candidate for chronic eye disease for which a New Drug Application (“NDA”) has been filed with the U.S. Food and Drug Administration (“FDA”) and two of the only three products approved by the FDA for the long-term, sustained release delivery of drug to treat chronic eye disease.

ILUVIEN®, the Company’s lead product candidate under FDA review, uses the third generation of the Durasert technology system to deliver fluocinolone acetonide (“FA”) over a period of up to 3 years for the treatment of Diabetic Macular Edema (“DME”). ILUVIEN is licensed to Alimera Sciences, Inc. (“Alimera”). Alimera has completed 36-month Phase III clinical trials for ILUVIEN for DME. Based on analysis of 24-month data released in December 2009, Alimera filed an NDA with the FDA in June 2010 and registration filings in various European countries in July 2010. On August 30, 2010, the FDA granted Priority Review status. In December 2010, the FDA issued a Complete Response Letter (“CRL”) which communicated the FDA’s decision that the NDA for ILUVIEN for DME could not be approved in its present form. In the CRL, the FDA requested analyses of safety and efficacy data through month 36, including exploratory analyses in addition to those analyses previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN, as well as other information. On February 3, 2011, Alimera reported top-line results from the 36-month readout of the completed clinical trials and reported that it intends to submit the data to the FDA by the end of the first calendar quarter. Under the Company’s collaboration agreement with Alimera, ILUVIEN is also being studied in investigator-sponsored pilot clinical trials designed to assess the safety and efficacy of ILUVIEN in both wet and dry Age-Related Macular Degeneration and Retinal Vein Occlusion.

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

The Company has a collaboration agreement with Pfizer, Inc. (“Pfizer”) which provides for a joint research program aimed at developing ophthalmic applications that are not licensed to others using certain of the Company’s technologies.

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

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The Company's future operating results may vary from year to year and quarter to quarter, and such variations could be significant. Future operating results are expected to depend upon the amounts of payments that may be received from, and revenue recognition associated with, its current and any potential future collaboration arrangements and the clinical development costs and outcomes of its product candidates. The Company anticipates that existing capital resources of \$14.6 million at December 31, 2010, together with approximately \$10.1 million of equity capital raised in January 2011 (see Note 11), should enable it to maintain its current and planned operations into at least calendar year 2013. The Company's ability to fund its planned operations internally beyond then may be substantially dependent upon the FDA approval of ILUVIEN, and the timing thereof, which would result in a \$25.0 million milestone payment due from Alimera, and the successful commercialization of ILUVIEN by Alimera.

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 discussed below, management 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. Stockholders' Equity

### Warrants to Purchase Common Shares

The following table provides a reconciliation of all US\$ warrants for the six months ended December 31, 2010 and 2009:

	Six Months Ended December 31,			
	2010		2009	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	7,062,248	\$ 7.53	7,162,248	\$ 7.50
Exercised	—	—	(100,000)	4.84
Balance and exercisable at end of period	<u>7,062,248</u>	<u>\$ 7.53</u>	<u>7,062,248</u>	<u>\$ 7.53</u>

At December 31, 2010, these outstanding warrants had a weighted average remaining life of 1.2 years.

The following table provides a reconciliation of all A\$ warrants for the six months ended December 31, 2010 and 2009:

	Six Months Ended December 31,			
	2010		2009	
	Number of Warrants	Weighted Average Exercise Price A\$	Number of Warrants	Weighted Average Exercise Price A\$
Balance at beginning of period	3,935,433	9.54	3,935,433	9.54
Expired	(716,538)	10.40	—	—
Balance and exercisable at end of period	<u>3,218,895</u>	<u>9.35</u>	<u>3,935,433</u>	<u>9.54</u>



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The weighted average exercise price of these warrants translated to \$ was \$9.51 at December 31, 2010 and \$8.52 at December 31, 2009. At December 31, 2010, these outstanding warrants had a weighted average remaining life of 3 months.

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, with a corresponding reduction in additional paid-in capital, subject to revaluation of the liability on a recurring basis through the statement of operations. The fair value of the warrants is determined using a Black-Scholes model. The net change in the fair values of these derivative liabilities resulted in income of \$458,000 for the three months ended December 31, 2010 compared to income of \$83,000 for the same period a year earlier and income of \$796,000 for the six months ended December 31, 2010 compared to expense of \$1.4 million a year earlier. The change in the fair value of these derivative liabilities is primarily attributable to the spread between the Company's share price and the US\$-equivalent exercise prices of the underlying warrants, and secondarily to the reduction of the remaining contractual life of the warrants.

### **3. License and Collaboration Agreements**

#### **Alimera Sciences, Inc.**

Under a collaboration agreement with Alimera, as amended in March 2008 (the "Alimera Agreement"), the Company 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 conditional note providing for aggregate principal and interest payments of up to approximately \$21.3 million through September 2012, Alimera agreed to pay a \$25.0 million milestone payment upon FDA approval of ILUVIEN, 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 and anticipated regulatory submissions. In exchange, the Company decreased its share in any future profits, as defined, on sales of ILUVIEN by Alimera from 50% to 20%, subject to an offset of 20% of pre-profitability commercialization costs, as defined, incurred by Alimera. In the event Alimera sublicenses commercialization, the Company is entitled to receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. On April 27, 2010, Alimera paid the \$15.0 million conditional note in full together with \$225,000 of accrued and unpaid interest.

The initial \$18.3 million of deferred revenue was recognized as revenue on a straight-line basis over the 21.5 month performance period from the effective date of the Alimera Agreement through December 31, 2009. All additional cash consideration received from Alimera during the performance period, which consisted of conditional note payments and development cost reimbursements, was recognized as revenue during the performance period using the cumulative catch-up method.

Revenue related to the Alimera Agreement totaled \$67,000 and \$121,000 for the three and six months ended December 31, 2010, respectively, compared to \$3.4 million and \$6.6 million for the three and six months ended December 31, 2009, respectively. These revenues represented the primary component of the Company's collaborative research and development revenue for these periods.

#### **Pfizer**

In April 2007, the Company and Pfizer entered into a worldwide collaborative research and license agreement (the "Pfizer Agreement"), which superseded a December 2006 research agreement, under which the Company licensed Pfizer certain of the Company's technologies for use in the development of ophthalmic applications not licensed to others. The Pfizer Agreement provides for a joint research program, for which Pfizer pays the Company a minimum of \$500,000 quarterly in consideration of the Company's costs in performing the research program. These quarterly payments continue until the earlier of the commencement of the first Phase III clinical trial for a licensed product candidate or the termination of the Pfizer Agreement. The agreement also provides for potential development and sales related milestone payments.

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Following an evaluation of the multiple deliverables, the Company determined that the Pfizer Agreement and the preceding Pfizer research agreement should be combined for accounting purposes as a single unit of accounting. The Company is unable to define the time period of its overall deliverables and other obligations under the Pfizer Agreement and, as a result, all payments received from Pfizer through December 31, 2010, totaling \$7.25 million, were classified in non-current deferred revenue.

### **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 remains in effect, Intrinsiq is obligated to pay the Company aggregate minimum royalties of \$3.6 million, of which \$450,000 was paid in July 2009, \$630,000 is due in January 2012, and the remaining \$2.5 million is due through April 2014.

Under the original agreement, the parties were obligated to enter into a manufacture and supply agreement, which was consummated effective as of February 1, 2009. Pursuant to the supply agreement, the Company leased to Intrinsiq certain equipment for its use in manufacturing BioSilicon material. Subject to its right to terminate the lease, Intrinsiq will acquire title to the equipment upon the remittance of lease payments totaling \$122,000 over the 2-year lease term, of which the first four payments of \$24,000 each were received through December 2010.

The Company determined that the equipment lease component represented a separate element of this arrangement. Using the relative fair value method prescribed under the authoritative guidance, the Company allocated the arrangement consideration between the lease and license deliverables. 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 is recognizing revenue for consideration allocated to the license arrangement on a straight-line basis over this period. The Company recognized collaborative research and development revenue of \$21,000 and \$41,000 for the three and six months ended December 31, 2010, respectively, compared to \$21,000 and \$81,000 for the three and six months ended December 31, 2009, respectively. The remaining balance of payments received, including minimum royalties, of \$1.1 million was recorded as deferred revenue at December 31, 2010.

### **Bausch & Lomb**

The Company’s Retisert and Vitrasert products were developed and commercialized under a 1992 licensing and development agreement with Bausch & Lomb. Pursuant to a subsequent collaboration agreement, Bausch & Lomb has a worldwide exclusive license to make and sell Vitrasert and our first-generation products (as defined in the agreement, including Retisert) in return for royalties based on sales.

In June 2005, the Company received a \$3.0 million advance from Bausch & Lomb in consideration of \$6.25 million of future Retisert royalties that otherwise would be payable to the Company. During the quarter ended June 30, 2010, Bausch & Lomb retained the final portion of these royalties otherwise payable under the advance royalty agreement. Accounts receivable from Bausch & Lomb totaled \$301,000 at December 31, 2010 and \$342,000 at June 30, 2010.

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**4. Intangible Assets**

The reconciliation of intangible assets for the six months ended December 31, 2010 and for the year ended June 30, 2010 is as follows:

	<b>Six Months Ended December 31, 2010</b>	<b>Year Ended June 30, 2010</b>
	(In thousands)	
<b>Patents and licences</b>		
Gross carrying amount at beginning of period	\$ 53,275	\$ 56,559
Foreign currency translation adjustments	907	(3,284)
Gross carrying amount at end of period	<u>54,182</u>	<u>53,275</u>
Accumulated amortization at beginning of period	(29,398)	(27,757)
Amortization expense	(1,633)	(3,289)
Foreign currency translation adjustments	(470)	1,648
Accumulated amortization at end of period	<u>(31,501)</u>	<u>(29,398)</u>
Net book value at end of period	<u>\$ 22,681</u>	<u>\$ 23,877</u>

The net book value of the Company's intangible assets is summarized as follows:

	<b>December 31, 2010</b>	<b>June 30, 2010</b>
	(In thousands)	
BioSilicon technology	\$ 15,310	\$ 15,979
Durasert technology	<u>7,371</u>	<u>7,898</u>
	<u>\$ 22,681</u>	<u>\$ 23,877</u>

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 \$822,000 for the three months ended December 31, 2010 compared to \$840,000 for the second quarter last year and \$1.6 million for the six months ended December 31, 2010 compared to \$1.7 million for the same period last year. The carrying value of intangible assets at December 31, 2010 of \$22.7 million is scheduled to be amortized on a straight-line basis over the remaining estimated useful life of 7 years, or approximately \$3.2 million per year.

**5. Marketable Securities**

The amortized cost, unrealized gain (loss) and fair value of the Company's available-for-sale marketable securities at December 31, 2010 and June 30, 2010 were as follows:

	<b>December 31, 2010</b>		
	<b>Amortized Cost</b>	<b>Unrealized Gain</b>	<b>Fair Value</b>
	(In thousands)		
Corporate bonds	\$ 3,413	\$ 3	\$ 3,416
U.S. Government obligations	1,402	—	1,402
Commercial paper	<u>2,448</u>	—	<u>2,448</u>
Total marketable securities	<u>\$ 7,263</u>	<u>\$ 3</u>	<u>\$ 7,266</u>

		<u>June 30, 2010</u>	
	<u>Amortized</u>	<u>Unrealized</u>	<u>Fair Value</u>
	<u>Cost</u>	<u>(Loss)</u>	
		(In thousands)	
Corporate bonds	\$ 1,304	\$ (2)	\$ 1,302
U.S. Government obligations	449	—	449
Commercial paper	300	—	300
Total marketable securities	<u>\$ 2,053</u>	<u>\$ (2)</u>	<u>\$ 2,051</u>

During the six months ended December 31, 2010, \$6.0 million of marketable securities were purchased and \$750,000 matured. At December 31, 2010, marketable securities had maturities ranging between one and eleven months, with a weighted average maturity of 4.3 months.

## 6. 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. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2 – Inputs are observable prices that are not quoted on active markets, but corroborated by market data.
- 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. The fair value hierarchy gives the lowest priority to Level 3 inputs.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At December 31, 2010 and June 30, 2010, substantially all of the Company's interest-bearing cash equivalent balances were concentrated in two institutional money market funds that have investments consisting primarily of certificates of deposit, commercial paper, time deposits, U.S. government agency securities, treasury bills and treasury repurchase agreements. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

The Company's marketable securities are classified within Level 1 or Level 2 on the basis of valuations using quoted market price or alternative pricing sources and models utilizing market observable inputs, respectively. The Company's derivative liabilities are classified as Level 3 and valued using the Black-Scholes model.

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The following table summarizes the Company's assets and liabilities carried at fair value measured on a recurring basis at December 31, 2010 and June 30, 2010 by valuation hierarchy:

	December 31, 2010			
	Total Carrying Value at December 31, 2010	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	(In thousands)			
<b>Assets:</b>				
Cash equivalents	\$ 4,932	\$ 4,932	\$ —	\$ —
Marketable securities	7,266	3,416	3,850	—
	<u>\$ 12,198</u>	<u>\$ 8,348</u>	<u>\$ 3,850</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Derivative liabilities	<u>\$ 514</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 514</u>
	June 30, 2010			
	Total Carrying Value at June 30, 2010	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	(In thousands)			
<b>Assets:</b>				
Cash equivalents	\$ 15,055	\$ 15,055	\$ —	\$ —
Marketable securities	2,051	1,302	749	—
	<u>\$ 17,106</u>	<u>\$ 16,357</u>	<u>\$ 749</u>	<u>\$ —</u>
<b>Liabilities:</b>				
Derivative liabilities	<u>\$ 1,310</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,310</u>

The Company's derivative liabilities were classified as Level 3 and valued using the Black-Scholes model. At December 31, 2010 and June 30, 2010, the fair values were derived by applying the following assumptions:

	December 31, 2010	June 30, 2010
Expected term (in years)	0.15 - 1.53	0.5 - 2.04
Stock volatility	95%	95%
Risk-free interest rate	0.09% - 0.46%	0.22% - 0.63%
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,	
	2010	2009	2010	2009
	(In thousands)			
Balance at beginning of period	\$ 972	\$ 2,490	\$ 1,310	\$ 971
Change in fair value of derivative - other income (expense)	458	83	796	(1,436)
Balance at end of period	<u>\$ 514</u>	<u>\$ 2,407</u>	<u>\$ 514</u>	<u>\$ 2,407</u>

## 7. Stock-Based Compensation

As of December 31, 2010, the Company had two shareholder-approved stock-based compensation plans: the 2008 Incentive Plan, as amended on November 19, 2009 (the “2008 Plan”), and the Employee Share Option Plan (the “Plan”).

### 2008 Incentive Plan

The 2008 Plan provides for the issuance of a maximum of 3,491,255 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, 2010:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life</u> (in years)	<u>Aggregate Intrinsic Value</u> (in thousands)
Outstanding at July 1, 2010	1,966,000	\$ 2.36		
Granted	762,980	3.45		
Forfeited	(8,000)	2.68		
Cancelled	(1,250)	1.81		
Outstanding at December 31, 2010	<u>2,719,730</u>	<u>\$ 2.66</u>	<u>8.58</u>	<u>\$ 6,659</u>
Outstanding at December 31, 2010 -vested or unvested and expected to vest	<u>2,644,582</u>	<u>\$ 2.66</u>	<u>8.58</u>	<u>\$ 6,475</u>
Exercisable at December 31, 2010	<u>996,750</u>	<u>\$ 2.23</u>	<u>8.12</u>	<u>\$ 2,866</u>

Option grants for the six months ended December 31, 2010 consisted of 371,705 options with ratable annual vesting over 4 years, 256,275 options with 2-year cliff vesting subject to performance and service conditions and 135,000 options issued to non-executive directors with 1-year cliff vesting. A total of 444,000 options vested during the six months ended December 31, 2010.

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, 2010 based on the following key assumptions:

	<u>Six Months Ended December 31, 2010</u>
Option life (in years)	3.50 - 6.25
Stock volatility	95%
Risk-free interest rate	1.13% - 2.35%
Expected dividends	0%

### Employee Share Option Plan

Following the Company’s reincorporation in the U.S. in June 2008, no further options have been or will be granted under the Plan.

The exercise prices of all outstanding options under the Plan at December 31, 2010 were in excess of the market price of the Company’s common shares at that date and, accordingly, the options had no aggregate intrinsic value at that date. A total of 37,500 options vested during the six months ended December 31, 2010.

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The following table provides a reconciliation of stock option activity under the Plan for the six months ended December 31, 2010:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u> A\$	<u>Weighted Average Remaining Contractual Life</u> (in years)	<u>Aggregate Intrinsic Value</u> A\$
Outstanding at July 1, 2010	185,312	14.91		
Cancelled	<u>(50,312)</u>	<u>36.80</u>		
Outstanding and exercisable at December 31, 2010	<u>135,000</u>	<u>6.75</u>	<u>1.58</u>	<u>—</u>

At December 31, 2010, translated into \$, the weighted average exercise price of outstanding and exercisable options was \$6.86.

### 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, 2010 and 2009, as follows:

	<u>Three Months Ended December 31,</u>		<u>Six Months Ended December 31,</u>	
	<u>2010</u>	<u>2009</u>	<u>2010</u>	<u>2009</u>
	(In thousands)			
Compensation expense from:				
Stock options	\$ 448	\$ 310	\$ 899	\$ 603
Issuance of fully vested shares	<u>—</u>	<u>110</u>	<u>—</u>	<u>110</u>
	<u>\$ 448</u>	<u>\$ 420</u>	<u>\$ 899</u>	<u>\$ 713</u>
	<u>Three Months Ended December 31,</u>		<u>Six Months Ended December 31,</u>	
	<u>2010</u>	<u>2009</u>	<u>2010</u>	<u>2009</u>
	(In thousands)			
Compensation expense included in:				
Research and development	\$ 108	\$ 71	\$ 209	\$ 169
General and administrative	<u>340</u>	<u>349</u>	<u>690</u>	<u>544</u>
	<u>\$ 448</u>	<u>\$ 420</u>	<u>\$ 899</u>	<u>\$ 713</u>

At December 31, 2010, there was \$2.6 million of unrecognized compensation expense related to unvested share-based payment awards under the Company's 2008 Plan, which is expected to be recognized as expense over a weighted average period of 1.65 years.

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### 8. 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 income tax expense of \$35,000 and \$44,000 for the three and six months ended December 31, 2010, respectively, primarily related to estimated U.S. federal income taxes, net of earned foreign research and development tax credits.

For the three and six months ended December 31, 2010 and 2009, the Company had no significant unrecognized tax benefits in the accompanying unaudited condensed consolidated financial statements. At December 31, 2010 and June 30, 2010, the Company had no accrued penalties or interest related to uncertain tax positions.

### 9. Loss Per Share

Basic net loss per share was computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share was computed by dividing the net loss by the sum of (i) the weighted average number of common shares outstanding and (ii) the weighted average number of common shares that would be issued on the conversion of all dilutive securities outstanding. Potentially dilutive shares were not included in the calculation of diluted net loss per share for each of the three and six month periods ended December 31, 2010 and 2009 as their inclusion would be anti-dilutive.

Potentially dilutive shares at December 31, 2010 and 2009 were as follows:

	December 31,	
	2010	2009
Options	2,854,730	2,339,125
Warrants	10,281,143	10,997,681
	<u>13,135,873</u>	<u>13,336,806</u>

### 10. Comprehensive (Loss) Income

Comprehensive (loss) income for the three and six month periods ended December 31, 2010 and 2009 was as follows:

	Three Months Ended December 31,		Six Months Ended December 31,	
	2010	2009	2010	2009
	(In thousands)			
Net loss	\$ (2,695)	\$ (24)	\$ (5,803)	\$ (1,615)
Foreign currency translation adjustments	(315)	25	402	(646)
Net unrealized gain on marketable securities	—	—	5	—
Comprehensive (loss) income	<u>\$ (3,010)</u>	<u>\$ 1</u>	<u>\$ (5,396)</u>	<u>\$ (2,261)</u>



**11. Subsequent Event**

On January 24, 2011, the Company completed a registered direct offering of 2,210,000 shares of its common stock and warrants to purchase 552,500 shares of its common stock to institutional investors for gross proceeds of \$11.05 million. The shares and warrants were sold in units, each unit consisting of one share together with 0.25 of one warrant, at a negotiated price of \$5.00 per unit. Each whole warrant has an exercise price of \$5.00 per share and a five-year term. Placement agent fees and other share issue costs are estimated to approximate \$925,000.

The Company has evaluated subsequent events from December 31, 2010 through the date of the issuance of these financial statements and has determined that no other material subsequent events have occurred that would affect the information presented in these financial statements or require additional disclosure.

## **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: ability to obtain additional capital uncertain; future losses; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; decline of royalty income from Bausch & Lomb; Alimera’s ability to obtain regulatory approval of ILUVIEN including analysis of results through month 36 of the FAME Study, safety and efficacy of ILUVIEN, controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN and cGMP at manufacturers of ILUVIEN; Alimera’s ability to successfully commercialize ILUVIEN if approved; risk/benefit profile of ILUVIEN; timeliness of approval, if any, of ILUVIEN and any limitations on uses thereof; ability to complete clinical trials and obtain regulatory approval of other product candidates; ability to find partners to develop and market products; termination of license agreements; competition; market acceptance of products and product candidates; reduction in use of products as a result of future publications; ability to protect intellectual property or infringement of others’ intellectual property; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; 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.

### **Our Business**

We develop tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. Once administered, a drug is released on a controlled and level basis for months or years. We have two core technology systems, Durasert™ and BioSilicon™. Utilizing three generations of our Durasert technology system, we have one product candidate for chronic eye disease for which a New Drug Application (“NDA”) has been filed with the U.S. Food and Drug Administration (“FDA”) and two of the only three products approved by the FDA for the long-term, sustained release delivery of drug to treat chronic eye disease.

ILUVIEN®, our lead product candidate under FDA review, is designed to provide sustained release treatment for Diabetic Macular Edema (“DME”). DME is a leading cause of vision loss for people under the age of 65 and has been estimated to affect over 1,000,000 people in the United States. Using the third-generation of our Durasert technology system, ILUVIEN is injected into the eye and delivers the corticosteroid fluocinolone acetonide (“FA”) over a period of up to 3 years. ILUVIEN is licensed to Alimera Sciences, Inc (“Alimera”). Under our collaboration agreement with Alimera, ILUVIEN is also being studied in investigator-sponsored pilot clinical trials designed to assess the safety and efficacy of ILUVIEN in both wet and dry Age-Related Macular Degeneration and Retinal Vein Occlusion.

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Alimera has completed 36-month Phase III clinical trials for ILUVIEN for DME. Based on analysis of 24-month data released in December 2009, Alimera filed an NDA with the FDA in June 2010 and registration filings in various European countries in July 2010. On August 30, 2010, the FDA granted Priority Review status. In December 2010, the FDA issued a Complete Response Letter (“CRL”) which communicated the FDA’s decision that the NDA for ILUVIEN for DME could not be approved in its present form. In the CRL, the FDA asked for analyses of safety and efficacy data through month 36, including exploratory analyses in addition to those analyses previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. In the CRL, the FDA also requested additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which Alimera reported it is in the process of compiling. Additionally, the FDA indicated in the CRL that it had observed deficiencies in current good manufacturing practices (“cGMP”) during facility inspections of two of Alimera’s third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls will need to comply with cGMP. Alimera has reported that its third-party manufacturers are in the process of resolving these deficiencies. On February 3, 2011, Alimera announced top-line results from the 36-month readout of the completed clinical trials and reported that it intends to submit the data to the FDA by the end of the first calendar quarter.

Our two FDA-approved products utilize 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 retinitis. We have licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated (“Bausch & Lomb”). Retisert provides sustained release treatment for approximately two and a half years, and Vitrasert provides sustained release treatment for six to nine months.

We have a collaboration agreement with Pfizer, Inc. (“Pfizer”), which provides for a joint research program aimed at developing ophthalmic applications that are not licensed to others using certain of our technologies.

BioSilicon, our other principal technology system, is a fully-erodible, nanostructured, porous silicon designed to provide sustained delivery of various therapeutics, including small drug molecules, proteins and peptides. Based on results of our preliminary studies, we are currently targeting BioSilicon as a key second prong of our drug delivery technology platform.

### **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, 2010 (“fiscal year 2010”), we set forth our critical accounting policies and estimates, which included revenue recognition and the carrying value 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 2010.

**Results of Operations****Three Months Ended December 31, 2010 Compared to Three Months Ended December 31, 2009:**

	<b>Three Months Ended December 31,</b>		<b>Change</b>	
	<b>2010</b>	<b>2009</b>	<b>Amounts</b>	<b>%</b>
	(In thousands except percentages)			
Revenues	\$ 414	\$ 3,433	\$(3,019)	(88)%
Operating expenses:				
Research and development	1,534	1,728	(194)	(11)%
General and administrative	2,001	1,818	183	10%
Total operating expenses	3,535	3,546	(11)	(0)%
Loss from operations	(3,121)	(113)	(3,008)	2,662%
Other income (expense):				
Change in fair value of derivatives	458	83	375	452%
Interest income	6	—	6	na
Other (expense) income, net	(3)	(4)	1	(25)%
Total other income (expense)	461	79	382	484%
Loss before income taxes	(2,660)	(34)	(2,626)	7,724%
Income tax (expense) benefit	(35)	10	(45)	(450)%
Net loss	<u>\$(2,695)</u>	<u>\$ (24)</u>	<u>\$(2,671)</u>	<u>11,129%</u>

**Revenues**

Revenues decreased by \$3.0 million, or 88%, to \$414,000 for the three months ended December 31, 2010 as compared to \$3.4 million for the three months ended December 31, 2009. On December 31, 2009, we completed the 21.5 month performance obligation period during which we amortized to revenues the consideration received from Alimera in connection with our 2008 amended collaboration agreement. Collaborative research and development revenue related to our Alimera collaboration agreement totaled \$67,000 for the three months ended December 31, 2010 as compared to \$3.4 million for the same period a year earlier.

We would be entitled to receive a \$25.0 million milestone payment from Alimera if the FDA approves ILUVIEN. Absent FDA approval of ILUVIEN during the fiscal year ending June 30, 2011 (“fiscal year 2011”), we currently expect to record an insignificant amount of collaborative research and development revenue attributable to the Alimera collaboration agreement in fiscal year 2011.

Pursuant to a June 2005 side letter to the collaboration agreement with Bausch & Lomb, we received \$3.0 million from Bausch & Lomb as an advance payment in lieu of \$6.25 million of future Retisert royalties that otherwise would have been payable to us. The advance royalty agreement was completed as of June 30, 2010. Royalty income from sales of Retisert for the three months ended December 31, 2010 totaled \$301,000 compared to \$373,000 of royalties that would otherwise have been payable for the three months ended December 31, 2009.

**Research and Development**

Research and development decreased by \$194,000, or 11%, to \$1.5 million for the three months ended December 31, 2010 from \$1.7 million for the three months ended December 31, 2009. The decrease was primarily attributable to a Federal grant of \$208,000 recorded in the three months ended December 31, 2010, which funded a portion of our research and development expense.

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### **General and Administrative**

General and administrative increased by \$183,000, or 10%, to \$2.0 million for the three months ended December 31, 2010 from \$1.8 million for the three months ended December 31, 2009. This increase was primarily attributable to increased professional fees and stock-based compensation.

### **Change in Fair Value of Derivatives**

Change in fair value of derivatives represented income of \$458,000 for the three months ended December 31, 2010 compared to income of \$83,000 for the three months ended December 31, 2009. This net change was due to an increasing spread between the US\$-equivalent weighted average exercise price of the A\$-denominated warrants and the market price of our common shares during the current period compared to the prior year period and the effect of the very short remaining weighted average life of these warrants (3 months at December 31, 2010).

Utilizing the Black-Scholes valuation model, we record the fair value of warrants denominated in A\$ as a derivative liability at each balance sheet date, and changes in their fair values result in corresponding income or expense in our statement of operations for those periods. Fluctuations in the fair values of these warrants, which could be substantial, particularly given their short remaining weighted average life, will continue to affect our operating results until the last-to-expire of these warrants in July 2012.

### **Income Tax (Expense) Benefit**

Income tax expense was \$35,000 for the three months ended December 31, 2010 compared to an income tax benefit of \$10,000 for the three months ended December 31, 2009. The net change was primarily attributable to a \$31,000 increase in U.S. federal alternative minimum tax expense and a \$14,000 reduction in foreign research and development tax credits.

### **Six Months Ended December 31, 2010 Compared to Six Months Ended December 31, 2009:**

	Six Months Ended December 31,		Change	
	2010	2009	Amounts	%
	(In thousands except percentages)			
Revenues	\$ 890	\$ 6,816	\$(5,926)	(87)%
Operating expenses:				
Research and development	3,276	3,528	(252)	(7)%
General and administrative	4,170	3,508	662	19%
Total operating expenses	7,446	7,036	410	6%
Loss from operations	(6,556)	(220)	(6,336)	2,880%
Other income (expense):				
Change in fair value of derivatives	796	(1,436)	2,232	155%
Interest income	12	2	10	500%
Other (expense) income, net	(11)	5	(16)	(320)%
Total other income (expense)	797	(1,429)	2,226	156%
Loss before income taxes	(5,759)	(1,649)	(4,110)	249%
Income tax (expense) benefit	(44)	34	(78)	(229)%
Net loss	\$(5,803)	\$(1,615)	\$(4,188)	259%

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### **Revenues**

Revenues decreased by \$5.9 million, or 87%, to \$890,000 for the six months ended December 31, 2010 from \$6.8 million for the six months ended December 31, 2009, reflecting the completion of the 21.5 month performance obligation period during which we amortized to revenues the consideration received from Alimera in connection with our 2008 amended collaboration agreement. Collaborative research and development revenue related to our Alimera collaboration agreement totaled \$121,000 for the six months ended December 31, 2010 as compared to \$6.6 million for the six months ended December 31, 2009.

Royalty income from sales of Retisert for the six months ended December 31, 2010 totaled \$674,000 compared to \$747,000 of royalties that would otherwise have been payable for the six months ended December 31, 2009 absent the royalty advance agreement.

### **Research and Development**

Research and development decreased by \$252,000, or 7%, to \$3.3 million for the six months ended December 31, 2010 compared to \$3.5 million for the six months ended December 31, 2009, primarily reflecting the \$208,000 grant discussed above.

### **General and Administrative**

General and administrative increased by \$662,000, or 19%, to approximately \$4.2 million for the six months ended December 31, 2010 from approximately \$3.5 million for the six months ended December 31, 2009. This increase was primarily attributable to increased professional fees and stock-based compensation.

### **Change in Fair Value of Derivatives**

Change in fair value of derivatives represented income of \$796,000 for the six months ended December 31, 2010 compared to expense of approximately \$1.4 million for the six months ended December 31, 2009. This net change was due to the increased spread between the US\$-equivalent weighted average exercise price of the A\$-denominated warrants and the market price of our common shares during the current period compared to a corresponding decrease in the spread for the prior year period and was also impacted by the very short remaining weighted average life of these warrants (3 months at December 31, 2010).

### **Income Tax (Expense) Benefit**

Income tax expense was \$44,000 for the six months ended December 31, 2010 compared to an income tax benefit of \$34,000 for the six months ended December 31, 2009. The net change was attributable to a \$52,000 increase in U.S. federal alternative minimum tax expense and a \$26,000 decrease of foreign research and development tax credits.

### **Liquidity and Capital Resources**

During the past three fiscal years, we have financed our operations primarily from license fees, research and development funding and contingent cash payments from our collaboration partners and, to a lesser degree, from a July 2007 private placement of our equity securities. At December 31, 2010, our principal sources of liquidity consisted of cash, cash equivalents and marketable securities totaling \$14.6 million. Our cash equivalents are invested in institutional money market funds and our marketable securities are invested in investment-grade corporate debt, government agency securities and commercial paper with maturities at December 31, 2010 ranging from 1 to 11 months. In January 2011, the Company completed a registered direct offering of 2,210,000 shares of its common stock and warrants to purchase 552,500 shares of its common stock to institutional investors for net proceeds of approximately \$10.1 million. We intend to use the net proceeds of this offering for general corporate purposes, which may include working capital, research and development expenditures, pre-clinical and clinical trial expenditures, capital expenditures, commercial expenditures, acquisitions of new technologies or businesses, and investments.

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With the exception of fiscal year 2010, we have incurred operating losses each year since inception and, at December 31, 2010, we had a total accumulated deficit of \$224.1 million. We generally expect negative cash flows from operations on a quarterly basis at least until such time as one or more of our product candidates achieves regulatory approval and sufficient revenues. We believe we can fund our operations as currently conducted into at least calendar year 2013. Whether we will require, or desire, additional capital will be influenced by many factors, including, but not limited to:

- the timely development and regulatory approval and successful commercialization of ILUVIEN and receipt of milestone, royalty and other payments;
- the scope and extent of our internally funded operations and programs, any new product candidates and any new business opportunities;
- our ability to establish and maintain strategic arrangements for products and product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan, including the pursuit of any new business opportunities, which may affect our need for capital.

Absent adequate levels of funding from new and existing collaboration agreements and/or financing transactions, management currently believes that our cash position thereafter depends significantly on approval of ILUVIEN by the FDA and foreign regulatory authorities and the initiation and success of marketing of ILUVIEN. However, there is no assurance that the FDA or other regulatory authorities will approve ILUVIEN or that ILUVIEN will achieve market acceptance even if it is approved.

If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. The state of the economy and the financial and credit markets at the time we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

Our consolidated statements of cash flows are summarized as follows:

	Six Months Ended December 31,		Change
	2010	2009 (In thousands)	
Net loss:	\$(5,803)	\$ (1,615)	\$(4,188)
Changes in operating assets and liabilities	1,176	(4,485)	5,661
Other adjustments to reconcile net loss to cash flows from operating activities	1,825	3,852	(2,027)
Net cash used in operating activities	<u>\$(2,802)</u>	<u>\$ (2,248)</u>	<u>\$ (554)</u>
Net cash used in investing activities	<u>\$(5,337)</u>	<u>\$ —</u>	<u>\$(5,337)</u>
Net cash provided by financing activities	<u>\$ —</u>	<u>\$ 484</u>	<u>\$ (484)</u>

Net cash used in operating activities increased by \$554,000 to \$2.8 million for the six months ended December 31, 2010 compared to \$2.2 million for the six months ended December 31, 2009. The net increase of cash used in operating activities consisted of a net increase in operating cash outflows, primarily attributable to higher professional fees.

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Net cash used in investing activities consisted predominantly of \$6.0 million of purchases, net of \$750,000 of maturities, of marketable securities during the six months ended December 31, 2010. No cash was used in investing activities for the six months ended December 31, 2009.

Net cash provided by financing activities of \$484,000 for the six months ended December 31, 2009 consisted of the exercise of investor warrants.

We had no borrowings or line of credit facilities as of December 31, 2010.

### Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2010 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, 2010, the balance of our derivative liabilities, which relate to warrants denominated in A\$, totaled \$514,000 and was determined using the Black-Scholes valuation model. The change in fair value of derivatives resulted in income of \$796,000 for the six months ended December 31, 2010 and expense of \$1.4 million for the six-month period a year earlier.

Our financial position and results of operations will continue to be sensitive to future revaluations of these derivative liabilities. At December 31, 2010, these warrants had a weighted average remaining contractual life of approximately 3.0 months and a weighted average exercise price of \$9.51 per share compared to the \$5.11 NASDAQ closing price of our common shares on that date. The primary factor that impacts the change in fair value of these derivatives is the change in the spread between our share price and the US\$-equivalent weighted average exercise price. Reduction of the remaining contractual life of the warrants, assuming that share price, volatility and A\$ to US\$ exchange rate remain constant, would result in a significant decrease of the derivative liability value during the remainder of fiscal year 2011. Changes in risk-free interest rates have a *de minimis* effect.

The following table summarizes the sensitivity of our consolidated statement of operations for the three months ended December 31, 2010 to assumed increases or decreases of our share price at December 31, 2010:

	Decrease in Share Price			Current Price (In thousands)	Increase in Share Price		
	-15%	-10%	-5%		+5%	+10%	+15%
Change in fair value of derivatives -income (expense)	<u>\$203</u>	<u>\$ 147</u>	<u>\$ 80</u>	<u>\$ —</u>	<u>\$(95)</u>	<u>\$(206)</u>	<u>\$(335)</u>

#### Foreign Currency Exchange Rates

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations, and the Pound Sterling is the functional currency for our U.K. operations. Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling impact the net operating expenses of our U.K. operations. For the three months ended December 31, 2010, the strengthening of the U.S. dollar compared to the comparable period of the prior year resulted in a net decrease in research and development expenses of \$27,000. 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.



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Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling also impact total stockholders' equity. At December 31, 2010, compared to September 30, 2010, the strengthening of the U.S. dollar in relation to the Pound Sterling resulted in a net decrease of \$315,000 in stockholders' equity due to the translation of £9.3 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, 2010 in relation to the Pound Sterling, our stockholders' equity at December 31, 2010 would have decreased or increased, respectively, by \$720,000.

### **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**

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2010. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under 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, 2010, 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 may be required to seek additional capital in order to fund our operations, and our ability to obtain additional capital is uncertain.*

Our cash, cash equivalents and marketable securities totaled approximately \$14.6 million at December 31, 2010. We raised net proceeds of approximately \$10.1 million in a registered direct offering completed on January 24, 2011. We believe we can fund our operations as currently conducted into at least calendar year 2013. Whether we will require, or desire, additional capital will be influenced by many factors, including, but not limited to:

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

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- the scope and extent of our internally funded operations and programs, and any new product candidates and any new business opportunities;
- our ability to establish and maintain strategic arrangements for products and product candidates for research, development, clinical testing, manufacturing and marketing;
- the success of our products and product candidates, including the timing and costs of regulatory approvals and the commercial success of approved products;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan, including the pursuit of any new business opportunities, which may affect our need for capital.

In particular, our future cash position depends significantly on approval of ILUVIEN by the FDA and foreign regulatory authorities and the initiation and success of marketing of ILUVIEN. Alimera has agreed to pay us \$25 million upon FDA approval of ILUVIEN for DME. In addition, we will be entitled to 20% of any future profits, as defined, on sales of ILUVIEN by Alimera, subject to an offset of 20% of defined pre-profitability commercialization costs incurred by Alimera. In the event Alimera sublicenses commercialization, we would receive 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. However, there is no assurance that the FDA or other regulatory authorities will approve ILUVIEN or that ILUVIEN will achieve market acceptance even if it is approved.

If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. The state of the economy and the financial and credit markets at the time we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs, postpone the pursuit of product candidates and new business opportunities, or otherwise reduce our cash requirements.

### ***We have a history of losses and may incur losses in the future.***

With the exception of fiscal year 2010, we have incurred operating losses since our inception in 2000. For fiscal year 2010, we recorded net income of \$8.8 million, primarily due to the accelerated payment in full by Alimera of a \$15.0 million conditional note. For the fiscal years ended June 30, 2009 and 2008, we incurred net losses of \$2.5 million and \$75.7 million, respectively. We incurred a net loss of \$5.8 million for the six months ended December 31, 2010 and expect to incur net losses for the balance of fiscal year 2011 and for the foreseeable future if ILUVIEN is not approved and successfully commercialized. Even if ILUVIEN is approved and marketed, our profit share on sales of ILUVIEN, combined with any royalty income from our current products, and any other sources of revenue, may not be sufficient to result in profitability on an ongoing basis.

### ***Our results could be adversely affected as a result of the impact of impairment of our intangible assets, which could adversely affect the price of our securities.***

Impairment charges on our intangible assets could have a material effect on our results of operations, which could, in turn, adversely affect the price of our securities. We recorded significant amounts of intangible assets in connection with earlier acquisitions. We took a \$60.1 million impairment charge on goodwill as of June 30, 2008 (which reduced the carrying value of our goodwill to zero) and a \$45.3 million impairment charge on the recorded value of our Durasert intangible asset as of June 30, 2007. We still had \$22.7 million of intangible assets on our balance sheet as of December 31, 2010, of which \$15.3 million related to our BioSilicon technology and \$7.4 million related to our Durasert technology. We will continue to conduct impairment analyses of our intangible assets as required, and we may be required to take impairment charges in the future, which could be significant.

### ***Our results could be adversely affected by non-cash charges due to fluctuations in the fair values of certain of our outstanding warrants, which could adversely affect the price of our securities.***

We previously issued warrants denominated in Australian dollars (A\$). The fair values of these warrants have been recorded as derivative liabilities on our balance sheet. We are required to assess the fair value of these warrants at each balance sheet date, and changes in their fair values result in adjustments to our recorded derivative liabilities,

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and corresponding gains or losses in our statements of operations. The fair values of these warrants are sensitive to changes in our share price, among other factors, and are measured using the Black-Scholes valuation model. Fluctuations in the fair values of these warrants could be substantial and will continue to affect our operating results until the last-to-expire of these warrants in July 2012.

### ***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:

- the timing, receipt and amount of payments, if any, from current and potential future collaboration partners, including, without limitation, collaborative research, milestone and royalty payments, and the revenue recognition policies related thereto;
- changes in accounting estimates, policies or principles;
- the entry into, or termination of, collaboration agreements;
- the scope, duration and effectiveness of our collaboration arrangements;
- the quarterly income or expense amounts recorded from the revaluation of our derivative liabilities;
- the amount of research and development costs, including pre-clinical studies and clinical trials, that we fund internally;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- impairment write-downs of one or more of our intangible assets.

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 a decrease 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 retained by Bausch & Lomb) and Vitrasert has 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 payments 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**

***We do not know if the FDA or other regulatory authorities will approve ILUVIEN for DME. If Alimera is unable to obtain regulatory approval for and successfully commercialize ILUVIEN, or experiences significant delays in doing so, our business will be materially harmed.***

Alimera will not be able to market ILUVIEN for DME in the U.S. unless and until it receives FDA approval. Our ability to generate significant revenues from this product depends on the ability of Alimera to obtain regulatory approval for and successfully commercialize ILUVIEN. Based on Alimera's analysis of the month 24 clinical readout of data from the FAME Study ("24 Month Data"), Alimera filed a New Drug Application ("NDA") for approval of the low dose of ILUVIEN in the United States in June 2010, followed by registration filings in Austria, France, Germany, Italy, Portugal and Spain in July 2010. The FDA accepted Alimera's submission and granted a Priority Review. The FDA issued a Complete Response Letter ("CRL") to Alimera in December 2010, which communicated the FDA's decision that the NDA for ILUVIEN for DME could not be approved in its present form.

In the CRL, the FDA asked for analyses of safety and efficacy of the clinical readout of data from the FAME Study through month 36 ("36 Month Data"), including certain exploratory analyses in addition to analyses previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN. In the CRL, the FDA requested additional information regarding controls and specifications concerning the manufacturing, packaging and sterilization of ILUVIEN, which Alimera reported it is in the process of compiling. Additionally, the FDA indicated

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in the CRL that it had observed deficiencies in current good manufacturing practices (“cGMP”) during facility inspections of two of Alimera’s third-party manufacturers, which were completed in August and September of 2010, and that all facilities and controls will need to comply with cGMP. Alimera has reported that its third-party manufacturers are in the process of resolving these deficiencies. On February 3, 2011, Alimera reported the top-line results of the 36-month readout of the FAME Study and reported that it intends to submit the data to the FDA by the end of the first calendar quarter.

In the NDA, Alimera included analyses of the 24 Month Data utilizing the full data set of all 956 patients randomized into Alimera’s FAME Study, with data imputation employed using “last observation carried forward” (“LOCF”) for data missing because of patients who discontinued the trial or were unavailable for follow-up (the “Full Analysis Set”) as well as other data sets including one that excludes from the Full Analysis Set three patients who were enrolled but never treated, excludes data collected for patients subsequent to their use of treatments prohibited by Alimera’s FAME Study protocol and imputes the last observation prior to the protocol violation forward to month 24 using the LOCF method (the “Modified ART Data Set”). Both Alimera and we believed that the FDA would consider the Full Analysis Set the most relevant population for determining the safety and efficacy of ILUVIEN based on the month 24 data. The primary efficacy endpoint at month 24 was met with statistical significance for both the low dose and the high dose of ILUVIEN in both trials using the Full Analysis Set. However, Alimera’s FAME Study protocol did not include the Full Analysis Set. The FAME Study protocol provides that the primary assessment of efficacy will be based on the Modified ART Data Set. Statistical significance was not achieved at month 24 for either the low dose or the high dose of ILUVIEN in one trial using the Modified ART Data Set. Although the CRL requested certain exploratory analyses with respect to the 36 Month Data, it did not specify what data set or sets Alimera should utilize to analyze the 36 Month Data. There is no assurance that the FDA will utilize the Full Analysis Set and not the Modified ART Data Set or another data set in determining whether ILUVIEN is safe and effective. We do not know whether any analyses of the 36 Month Data will demonstrate to the FDA that ILUVIEN is safe and efficacious.

In order to obtain approval to market ILUVIEN for DME in the U.S., Alimera will need to demonstrate to the FDA that ILUVIEN for DME is safe and efficacious and satisfy the FDA on each of the issues raised in the CRL. There is no assurance that the 36 Month Data or other responses provided by Alimera and its third-party manufacturers will be sufficient to satisfy the FDA. The FDA may not grant marketing approval or it may request additional information from Alimera, including requesting data from additional clinical trials, and ultimately may not grant marketing approval for ILUVIEN. In addition, Alimera will also require regulatory approvals to sell ILUVIEN for DME in other countries, and there is no assurance that it will receive those approvals.

If Alimera is not successful in obtaining regulatory approval for and commercializing ILUVIEN for DME, or is significantly delayed in doing so, our business will be materially harmed. Alimera’s ability to successfully obtain regulatory approval for and commercialize ILUVIEN will depend on, among other things, its ability to:

- receive marketing approval from the FDA and similar foreign regulatory authorities;
- maintain commercial manufacturing arrangements with third-party manufacturers;
- produce, or have its third-party manufacturers produce, sufficient quantities of ILUVIEN in a validated process to permit successful commercialization;
- launch commercial sales of ILUVIEN; and
- secure acceptance of ILUVIEN in the medical community and with third-party payors.

Alimera reported that it expects to obtain a regulatory agency waiver from the requirement to perform carcinogenicity studies of ILUVIEN in animals. Alimera’s month 18 readouts from its open-label Phase II human pharmacokinetic clinical trial (the “PK Study”) indicated to Alimera that there is negligible systemic absorption of fluocinolone acetonide (“FA”) in patients being treated with ILUVIEN. However, Alimera may be unable to demonstrate negligible systemic absorption of FA in its PK Study beyond month 18, or may not obtain a regulatory agency waiver from the requirement to perform carcinogenicity studies of ILUVIEN in animals regardless. Alimera reported that if it is required to perform carcinogenicity studies of ILUVIEN in animals, the approval of ILUVIEN could be delayed by up to 36 months.

***ILUVIEN utilizes FA, a corticosteroid that has demonstrated undesirable side effects in the eye, and the success of ILUVIEN, therefore, will be dependent upon achieving an acceptable risk/benefit profile.***

ILUVIEN utilizes FA, a corticosteroid whose use in the eye has been associated with undesirable side effects such as increased incidence of intraocular pressure (“IOP”), which may increase the risk of glaucoma and cataract formation. Alimera has performed a full analysis of only the month 24 clinical data from its FAME Study, and the extent of ILUVIEN’s long-term side-effect profile is not yet known. Upon review of Alimera’s NDA for the low dose of ILUVIEN in the treatment of DME as well as the analysis of the 36 Month Data, the FDA may conclude that Alimera’s FAME Study did not demonstrate that ILUVIEN has sufficient levels of efficacy to outweigh the risks associated with its side-effect profile. Conversely, the FDA may conclude that ILUVIEN’s side-effect profile does not demonstrate an acceptable risk/benefit relationship in line with ILUVIEN’s demonstrated efficacy. In the event of such conclusions, Alimera may not receive regulatory approval from the FDA or from similar regulatory agencies in other countries.

***Even if Alimera receives regulatory approval for ILUVIEN, the FDA and other regulatory agencies may impose limitations on the indicated uses for which ILUVIEN may be marketed, may subsequently withdraw approval for ILUVIEN or may take other actions against ILUVIEN that would be adverse to our business.***

Regulatory agencies generally approve products for particular indications. If any regulatory agency approves ILUVIEN for a limited indication, the size of the potential market for ILUVIEN will be reduced. For example, the potential market for ILUVIEN would be reduced if the FDA limited the indications of use to only those patients who had previously undergone cataract surgery or to those patients diagnosed with particularly severe DME as opposed to all those diagnosed with clinically significant DME.

Additionally, product approvals, once granted, may be withdrawn if problems occur after initial marketing. If and when ILUVIEN does receive regulatory approval or clearance, the marketing, distribution and manufacture of ILUVIEN will be subject to regulation by the FDA in the United States and by similar entities in other countries. Alimera will need to comply with facility registration and product listing requirements of the FDA and similar entities in other countries, and will need to adhere to the FDA’s Quality System Regulations. Noncompliance with applicable FDA and similar entities’ requirements could result in warning letters, fines, injunctions, civil penalties, recall or seizure of ILUVIEN, total or partial suspension of production, refusal of regulatory agencies to grant approvals, withdrawal of approvals by regulatory agencies or criminal prosecution. Alimera also will need to maintain compliance with federal, state and foreign laws regarding sales incentives, referrals and other programs.

***If we or our licensees are unable to 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. Generally, in order to obtain these approvals, pre-clinical studies and clinical trials must demonstrate that each of these product candidates is safe for human use and effective for its targeted disease or condition.

Our product candidates, other than ILUVIEN for DME, are in early stages of development. Product development involves a high degree of risk, and only a small proportion of research and development programs result in an approved product. If clinical trials that may be conducted by us or our licensees for any of our product candidates do not provide the necessary evidence of safety and effectiveness, those product candidates could not be manufactured and sold, and would not generate revenues. Clinical trials initiated by us or our licensees for product candidates may fail or be delayed by 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 reach agreement with a licensee to undertake the clinical trials;
- adverse side effects;
- failure of the trials to demonstrate a product’s safety and efficacy;
- our (or our licensees’) failure to meet FDA or other regulatory agency requirements for clinical trial design;

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- our (or our licensees') inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- failures by, or changes in our (or our licensees') relationship with, 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;
- 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; and
- governmental or regulatory delays, or changes in approval policies or regulations.

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.

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 marketing or commercialization partners, or our marketing or commercialization 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, Inc. ("Pfizer"), Bausch & Lomb and Intrinsic Materials Cayman Limited. 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;

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- 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, limiting the areas of research and development 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 financial 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, disagreements over rights or technologies or other proprietary interests may occur.

We have exclusively licensed certain of our controlled drug delivery technologies to Pfizer for certain ophthalmic applications. We have negotiated and continue to negotiate with Pfizer about potential amendments to the agreement, but we cannot predict whether or how that agreement will be amended. Pfizer may terminate the agreement 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 the 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 or to 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 if approved, ILUVIEN would be its 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 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

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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. 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 reduce demand for our products and product candidates and could 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, 2010, we had 168 patents and 164 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 some or all of our key personnel, our business could suffer.***

We are dependent upon the principal members of our management, administrative and scientific staff. In addition, we believe that our future success in developing our products and achieving a competitive position will depend to a large extent on whether we can attract and retain additional qualified management and scientific personnel. There is strong competition for such personnel within the industry in which we operate and we may not be able to continue to attract such personnel either to Massachusetts, where much of our research and development is conducted, or to Malvern in the U.K. As we have a small number of employees and our products are unique and highly specialized, the loss of the services of one or more of the 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 encounter problems with product manufacturing, we could experience delays in product development and commercialization, which would adversely affect our future profitability.***

Our ability 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 collaborative partners' 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. 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 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 regulations that are both capable of manufacturing our products and product candidates and are willing to do so. 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 current reliance on third-party manufacturers entails risks, including:

- the possibility that third parties may not comply with the FDA's cGMP regulations, other regulatory requirements, and those of similar foreign regulatory bodies, and may not employ adequate quality assurance practices;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or inconvenient to us; and

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- our inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

Alimera has contracted with third party manufacturers with respect to the manufacture of the components of ILUVIEN. Our business could be significantly harmed if these third parties are not able to manufacture ILUVIEN in compliance with cGMP or to satisfy demand for ILUVIEN and alternative sources are not available. In addition, the materials necessary to produce ILUVIEN or to formulate the active pharmaceutical ingredient may not be available on commercially reasonable terms, or at all, which could affect the development and commercialization of ILUVIEN.

***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 we intend to license products for sale and/or sell products in most major world healthcare markets. A number of risks are inherent in our international strategy. In order for us to license and manufacture our products, we must obtain country and jurisdiction-specific regulatory approvals or clearances to comply with regulations regarding safety and quality. We may not be able to obtain or maintain regulatory approvals or clearances in such countries, and we may be required to incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances. In addition, our operations and 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 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.

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The U.S. Food and Drug Administration Amendment 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 CHESSE Depositary Interests (CDIs)) may be affected by developments directly affecting our business and by developments out of our control or unrelated to us. 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, operating 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 trial results and other product and technological developments and innovations;
- FDA and other governmental regulatory actions, receipt and timing of approvals of our (or our licensees') 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 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 the royalties payable 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.

#### ***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 January 31, 2011, we had outstanding approximately 10.8 million warrants and 2.9 million options to acquire shares of our common stock, or approximately 39.8% of our shares on a fully diluted basis. Certain of the options are subject to performance conditions, and the exercise prices of substantially all of these warrants and a small portion of the stock options were above the market price at that date. The issuance of shares of our common stock upon exercise of our outstanding warrants and stock options would 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.

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***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 January 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

### **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 10, 2011

By: /s/ Paul Ashton

Name: Paul Ashton

Title: President and Chief Executive Officer

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

I, Paul Ashton, certify that:

1. I have reviewed this quarterly report on Form 10-Q of pSivida Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 10, 2011

/s/ Paul Ashton

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

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

I, Leonard S. Ross, certify that:

1. I have reviewed this quarterly report on Form 10-Q of pSivida Corp.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 10, 2011

/s/ Leonard S. Ross

Name: Leonard S. Ross

Title: Vice President, Finance

(Principal Financial Officer)

**Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

In connection with the Quarterly Report of pSivida Corp. (the "Company") on Form 10-Q for the quarter ended December 31, 2010, 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 10, 2011

/s/ Paul Ashton

Name: Paul Ashton

Title: President and Chief Executive Officer  
(Principal Executive Officer)



**Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

In connection with the Quarterly Report of pSivida Corp. (the "Company") on Form 10-Q for the quarter ended December 31, 2010, 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 10, 2011

/s/ Leonard S. Ross

Name: Leonard S. Ross

Title: Vice President, Finance  
(Principal Financial Officer)