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

FORM 10-Q

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

For the quarterly period ended March 31, 2014

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER 000-51122

pSivida Corp.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

02472
(Zip Code)

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

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

There were 29,252,458 shares of the registrant’s common stock, \$0.001 par value, outstanding as of May 9, 2014.

[Table of Contents](#)

PSIVIDA CORP. AND SUBSIDIARIES
INDEX TO FORM 10-Q

	<u>Page</u>
PART I: FINANCIAL INFORMATION	
Item 1. Unaudited Financial Statements	
Condensed Consolidated Balance Sheets – March 31, 2014 and June 30, 2013	3
Condensed Consolidated Statements of Comprehensive Loss – Three and Nine Months Ended March 31, 2014 and 2013	4
Condensed Consolidated Statement of Stockholders' Equity – Nine Months Ended March 31, 2014	5
Condensed Consolidated Statements of Cash Flows – Nine Months Ended March 31, 2014 and 2013	6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	16
Item 3. Quantitative and Qualitative Disclosures about Market Risk	22
Item 4. Controls and Procedures	23
PART II: OTHER INFORMATION	
Item 1A. Risk Factors	23
Item 6. Exhibits	23
Signatures	24
Certifications	

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements

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

	March 31, 2014	June 30, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,555	\$ 6,899
Marketable securities	2,712	3,374
Accounts and other receivables	613	597
Prepaid expenses and other current assets	582	1,594
Total current assets	22,462	12,464
Property and equipment, net	292	179
Intangible assets, net	2,940	3,430
Other assets	177	176
Restricted cash	150	—
Total assets	\$ 26,021	\$ 16,249
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 761	\$ 671
Accrued expenses	1,203	1,894
Deferred revenue	312	738
Total current liabilities	2,276	3,303
Deferred revenue	5,388	5,246
Deferred rent	11	—
Total liabilities	7,675	8,549
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$.001 par value, 60,000,000 shares authorized, 29,244,608 and 23,297,011 shares issued and outstanding at March 31, 2014 and June 30, 2013, respectively	29	23
Additional paid-in capital	290,344	270,415
Accumulated deficit	(273,046)	(263,658)
Accumulated other comprehensive income	1,019	920
Total stockholders' equity	18,346	7,700
Total liabilities and stockholders' equity	\$ 26,021	\$ 16,249

See notes to condensed consolidated financial statements

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

	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2014	2013	2014	2013
Revenues:				
Collaborative research and development	\$ 1,676	\$ 239	\$ 2,149	\$ 603
Royalty income	316	274	1,032	1,048
Total revenues	<u>1,992</u>	<u>513</u>	<u>3,181</u>	<u>1,651</u>
Operating expenses:				
Research and development	2,269	1,587	7,267	4,685
General and administrative	1,946	1,738	5,468	5,016
Gain on sale of property and equipment	(4)	—	(76)	—
Total operating expenses	<u>4,211</u>	<u>3,325</u>	<u>12,659</u>	<u>9,701</u>
Loss from operations	<u>(2,219)</u>	<u>(2,812)</u>	<u>(9,478)</u>	<u>(8,050)</u>
Other income (expense):				
Interest income	1	3	3	14
Other expense, net	—	—	—	(2)
Total other income	<u>1</u>	<u>3</u>	<u>3</u>	<u>12</u>
Loss before income taxes	(2,218)	(2,809)	(9,475)	(8,038)
Income tax benefit	31	15	87	85
Net loss	<u>\$ (2,187)</u>	<u>\$ (2,794)</u>	<u>\$ (9,388)</u>	<u>\$ (7,953)</u>
Net loss per common share - basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.12)</u>	<u>\$ (0.35)</u>	<u>\$ (0.35)</u>
Weighted average common shares - basic and diluted	<u>27,672</u>	<u>23,297</u>	<u>26,842</u>	<u>22,960</u>
Net loss	<u>\$ (2,187)</u>	<u>\$ (2,794)</u>	<u>\$ (9,388)</u>	<u>\$ (7,953)</u>
Other comprehensive income (loss):				
Foreign currency translation adjustments	5	(87)	100	(31)
Net unrealized (loss) gain on marketable securities	(1)	—	(1)	3
Other comprehensive income (loss)	<u>4</u>	<u>(87)</u>	<u>99</u>	<u>(28)</u>
Comprehensive loss	<u>\$ (2,183)</u>	<u>\$ (2,881)</u>	<u>\$ (9,289)</u>	<u>\$ (7,981)</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, 2013	23,297,011	\$ 23	\$270,415	\$ (263,658)	\$ 920	\$ 7,700
Net loss	—	—	—	(9,388)	—	(9,388)
Other comprehensive income	—	—	—	—	99	99
Issuance of stock, net of issue costs	5,576,112	6	18,057	—	—	18,063
Exercise of stock options	371,485	—	909	—	—	909
Stock-based compensation	—	—	963	—	—	963
Balance at March 31, 2014	<u>29,244,608</u>	<u>\$ 29</u>	<u>\$290,344</u>	<u>\$ (273,046)</u>	<u>\$ 1,019</u>	<u>\$ 18,346</u>

See notes to condensed consolidated financial statements

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

	Nine Months Ended	
	March 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$ (9,388)	\$ (7,953)
Adjustments to reconcile net loss to cash flows from operating activities:		
Amortization of intangible assets	582	578
Depreciation of property and equipment	103	168
Stock-based compensation expense	963	918
Amortization of bond premium on marketable securities	26	123
Gain on sale of property and equipment	(76)	—
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	1,016	(122)
Accounts payable and accrued expenses	(833)	785
Deferred revenue	(290)	138
Deferred rent	11	—
Net cash used in operating activities	<u>(7,886)</u>	<u>(5,365)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(2,714)	(7,758)
Maturities of marketable securities	3,350	11,884
Purchases of property and equipment	(75)	(49)
Proceeds from sale of property and equipment	76	—
Change in restricted cash	(150)	—
Net cash provided by investing activities	<u>487</u>	<u>4,077</u>
Cash flows from financing activities:		
Proceeds from issuance of stock, net of issuance costs	18,149	4,669
Exercise of stock options	909	—
Net cash provided by financing activities	<u>19,058</u>	<u>4,669</u>
Effect of foreign exchange rate changes on cash and cash equivalents	<u>(3)</u>	<u>(8)</u>
Net increase in cash and cash equivalents	11,656	3,373
Cash and cash equivalents at beginning of period	6,899	4,625
Cash and cash equivalents at end of period	<u>\$18,555</u>	<u>\$ 7,998</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of property and equipment	\$ 141	\$ 14
Stock issuance costs	86	—

See notes to condensed consolidated financial statements

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

1. Operations and Basis of Presentation

The accompanying condensed consolidated financial statements of pSivida Corp. and subsidiaries (the “Company”) as of March 31, 2014 and for the three and nine months ended March 31, 2014 and 2013 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, 2013. 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, 2013, and include all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair presentation of the Company’s financial position, results of operations, comprehensive loss and cash flows for the periods indicated. The preparation of financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”) requires management to make assumptions and estimates that affect, among other things, (i) reported amounts of assets and liabilities; (ii) disclosure of contingent assets and liabilities at the date of the consolidated financial statements; and (iii) reported amounts of revenues and expenses during the reporting period. The results of operations for the three and nine months ended March 31, 2014 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 products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Using its core technology platforms, Durasert™ and BioSilicon™, the Company is focused on treatment of chronic diseases of the back of the eye and is also exploring applications outside ophthalmology. The Company has developed three of the four sustained-release products for treatment of retinal diseases that have been approved in the U.S. or European Union (“EU”), and its lead development product began a Phase III clinical trial in the quarter ended June 2013. The Company’s strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

ILUVIEN®, the Company’s most recently approved product, is an injectable, sustained-release micro-insert that releases drug over a period of up to three years. It is approved in six EU countries for the treatment of vision impairment associated with chronic diabetic macular edema (“DME”) considered insufficiently responsive to available therapies. ILUVIEN is licensed to Alimera Sciences, Inc. (“Alimera”), and the Company is entitled to 20% of the net profits (as defined) from Alimera’s sales of ILUVIEN on a country-by-country basis. Alimera commenced the commercial launch of ILUVIEN for chronic DME in the U.K. and Germany in 2013 and plans to launch in France in 2014. Initially available in the U.K. only to private pay and privately insured patients, Alimera commenced shipments of ILUVIEN for chronic DME to U.K. National Health Service (“NHS”) facilities in January 2014 following ILUVIEN’s acceptance by the U.K.’s National Institute for Health and Care Excellence (“NICE”) as a treatment option for pseudophakic eyes (those that have had cataract surgery) subject to a simple patient access scheme. In February 2014, the Scottish Medicines Consortium (“SMC”) accepted ILUVIEN for use within NHS Scotland under a similar patient access scheme for pseudophakic eyes. In addition, Alimera has filed for ten additional EU country approvals through the Mutual Recognition Procedure.

In April 2014, Alimera entered into an exclusive agreement with Specialized Therapeutics Australia (“STA”) for the distribution of ILUVIEN in Australia and New Zealand. STA is responsible for regulatory and commercial matters, including marketing approval and reimbursement, in those countries. The agreement between Alimera and STA includes a milestone payment to Alimera upon achievement of a public reimbursement listing, and royalties based on net sales that will increase if a sales target is met. The Company is entitled to 20% of any royalties and 33% of all other payments received by Alimera, including any milestone payment.

Alimera resubmitted a New Drug Application (“NDA”) for ILUVIEN for chronic DME to the U.S. Food and Drug Administration (“FDA”) in March 2014 and the FDA set a new Prescription Drug User Fee Act (“PDUFA”) goal date of September 26, 2014. The NDA responded to questions raised in an October 2013 third Complete Response Letter (“CRL”) from the FDA, which identified concerns regarding the benefit to risk and safety profiles of ILUVIEN for chronic DME and stated that the NDA could not be approved in its then present form. The NDA also

Table of Contents

provided data from ILUVIEN patients and from physician experience with ILUVIEN's applicator in Germany and the U.K., and addressed deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. FDA approval of ILUVIEN would entitle the Company to a \$25.0 million milestone payment.

Medidur™, the Company's lead development product, is an injectable, sustained-release micro-insert being developed for the treatment of chronic non-infectious uveitis affecting the posterior of the eye ("posterior uveitis"). Medidur uses the same Durasert micro-insert and delivers the same dose of the same drug as ILUVIEN, which is a lower dose of the same drug as the Company's FDA-approved Retisert® for posterior uveitis. In the quarter ended June 2013, the Company commenced a Phase III clinical trial of Medidur. The Company originally planned to request FDA approval of Medidur on the basis of two Phase III trials, but now plans to seek FDA approval based on data from the currently ongoing Phase III trial, combined with clinical data about the Company's proprietary inserter, if ILUVIEN is approved by the FDA. The Company plans to have a confirmatory meeting with the FDA with respect to the Company's regulatory strategy as more data become available. If ILUVIEN is not approved by the FDA, the Company plans to file for FDA approval as originally planned. The Company is developing Medidur independently.

Retisert, an implant that provides sustained release treatment of posterior uveitis for approximately two and a half years, is licensed to and sold by Bausch & Lomb.

The Company is engaged in pre-clinical research with respect to its BioSilicon and Durasert technology platforms. The primary focus of the Company's BioSilicon research is the use of Tethadur™ for the sustained delivery of peptides, proteins and antibodies in both ophthalmic and non-ophthalmic applications. The Company's research program also includes the use of Durasert technology in orthopedic applications and for systemic delivery of therapeutic agents.

The Company is also developing a bioerodible, injectable micro-insert delivering latanoprost (the "Latanoprost Product") to treat glaucoma and ocular hypertension. Under an amended collaboration agreement, Pfizer Inc. ("Pfizer") has an option, under certain circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

The Company has a history of operating losses and has financed its operations primarily from the proceeds of sales of its equity securities and the receipt of license fees, research and development funding, royalties and contingent cash payments from its collaboration partners. The Company believes that its cash, cash equivalents and marketable securities of \$21.3 million at March 31, 2014, together with expected cash inflows under existing collaboration agreements, will enable the Company to maintain its current and planned operations through the third quarter of calendar year 2015. This estimate includes expected costs of clinical development of Medidur, but excludes any potential milestone or net profits receipts under the Alimera collaboration agreement. The Company's ability to fund its planned operations beyond then, including completion of clinical development of Medidur, is expected to depend on the amount and timing of cash receipts under the Alimera collaboration agreement, as well as proceeds from any future collaboration or other agreements and/or financing transactions.

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

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

2. License and Collaboration Agreements

Alimera

Under the collaboration agreement with Alimera, as amended in March 2008 (the "Alimera Agreement"), the Company licensed to Alimera the rights to develop, market and sell certain product candidates, including ILUVIEN, and Alimera assumed all financial responsibility for the development of licensed products. The Company is entitled to receive a \$25.0 million milestone payment from Alimera within 30 days following an FDA approval of ILUVIEN. In addition, the Company is entitled to receive 20% of any net profits (as defined) on sales of each licensed product (including ILUVIEN) by Alimera, measured on a quarter-by-quarter and country-by-country basis. Alimera may recover 20% of previously incurred and unapplied net losses (as defined) for

[Table of Contents](#)

commercialization of each product in a country, but only by an offset of up to 4% of the net profits earned in that country each quarter, reducing the Company's net profit share to 16% in each country until those net losses are recouped. In the event that Alimera sublicenses commercialization in any country, the Company is entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions.

Because the Company's performance obligations ended on December 31, 2009, amounts received thereafter under the Alimera Agreement are recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amounts are both fixed and determinable and reasonably assured of collectability.

Revenue related to the Alimera Agreement totaled \$47,000 and \$5,000 for the three months ended March 31, 2014 and 2013, respectively, and \$95,000 and \$44,000 for the nine months ended March 31, 2014 and 2013, respectively, and consisted of patent fee reimbursements.

Pfizer

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

As a result of the material modification of the Pfizer arrangement, the estimated selling price of the combined deliverables under the Restated Pfizer Agreement of \$6.7 million is being recognized as collaborative research and development revenue over the expected performance period of six years using the proportional performance method. The Company recorded revenue of \$9,000 and \$85,000 for the three months ended March 31, 2014 and 2013, respectively, and \$65,000 and \$336,000 for the nine months ended March 31, 2014 and 2013, respectively. Total deferred revenue was \$5.5 million and \$5.6 million at March 31, 2014 and June 30, 2013, respectively. Costs associated with developing the Latanoprost Product are reflected in operating expenses in the period in which they are incurred.

Pfizer owned approximately 6.4% of the Company's outstanding common stock at March 31, 2014.

Bausch & Lomb

Pursuant to a licensing and development agreement, as amended, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert in return for royalties based on sales. Bausch & Lomb was also licensed to make and sell Vitrasert, an implant for sustained treatment of CMV retinitis, but discontinued sales in the second quarter of fiscal 2013 following patent expiration.

Royalty income totaled \$316,000 and \$274,000 for the three months ended March 31, 2014 and 2013, respectively, and \$1.0 million for each of the nine month periods ended March 31, 2014 and 2013. Accounts receivable from Bausch & Lomb totaled \$316,000 at each of March 31, 2014 and June 30, 2013.

Enigma Therapeutics

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with Enigma Therapeutics Limited (“Enigma”) for the development of BrachySil, the Company’s BioSilicon product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of \$100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. Enigma is obligated to pay an annual license maintenance fee of \$100,000 by the end of each calendar year, the first of which was received in January 2014. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any patent maintenance costs, sales-based royalties and sublicensee sales-based royalties earned to the extent such amounts, in the aggregate, exceed the \$100,000 annual license maintenance fee. The Company has no consequential performance obligations under the Enigma license agreement and, accordingly, any amounts to which the Company is entitled under the agreement are recognized as revenue on the earlier of receipt or when collectability is reasonably assured. Revenue related to the Enigma agreement totaled \$0 and \$100,000 for the three months ended March 31, 2014 and 2013, respectively and \$102,000 and \$100,000 for the nine months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, no deferred revenue was recorded for this agreement.

Evaluation Agreements

The Company from time to time enters into funded agreements to evaluate the potential use of its technology systems for sustained release of third party drug candidates in the treatment of various diseases. Consideration received is generally recognized as revenue over the term of the feasibility study agreement. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the evaluation agreement. Revenues under evaluation agreements totaled \$1.6 million and \$48,000 for the three months ended March 31, 2014 and 2013, respectively, and \$1.9 million and \$123,000 for the nine months ended March 31, 2014 and 2013, respectively.

3. Intangible Assets

The reconciliation of intangible assets for the nine months ended March 31, 2014 and for the year ended June 30, 2013 was as follows (in thousands):

	<u>Nine Months Ended March 31, 2014</u>	<u>Year Ended June 30, 2013</u>
Patented technologies		
Gross carrying amount at beginning of period	\$ 38,941	\$ 39,556
Foreign currency translation adjustments	2,158	(615)
Gross carrying amount at end of period	41,099	38,941
Accumulated amortization at beginning of period	(35,511)	(35,330)
Amortization expense	(582)	(769)
Foreign currency translation adjustments	(2,066)	588
Accumulated amortization at end of period	(38,159)	(35,511)
Net book value at end of period	<u>\$ 2,940</u>	<u>\$ 3,430</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 \$196,000 and \$192,000 for the three months ended March 31, 2014 and 2013, respectively, as well as \$582,000 and \$578,000 for the nine months ended March 31, 2014 and 2013, respectively. The carrying value of intangible assets at March 31, 2014 of \$2.9 million (approximately \$2.0 million attributable to the Durasert technology and \$0.9 million attributable to the BioSilicon technology) is expected to be amortized on a straight-line basis over the remaining estimated useful life of 3.75 years, or approximately \$784,000 per year.

[Table of Contents](#)

4. Marketable Securities

The amortized cost, unrealized loss and fair value of the Company's available-for-sale marketable securities at March 31, 2014 and June 30, 2013 were as follows (in thousands):

	March 31, 2014		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	\$ 2,464	\$ (2)	\$ 2,462
Commercial paper	250	—	250
Total marketable securities	<u>\$ 2,714</u>	<u>\$ (2)</u>	<u>\$ 2,712</u>

	June 30, 2013		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	\$ 2,376	\$ (1)	\$ 2,375
Commercial paper	999	—	999
Total marketable securities	<u>\$ 3,375</u>	<u>\$ (1)</u>	<u>\$ 3,374</u>

During the nine months ended March 31, 2014, \$2.7 million of marketable securities were purchased and \$3.4 million of such securities matured. At March 31, 2014, the marketable securities had maturities ranging from 6 to 11.5 months, with a weighted average maturity of 10 months.

5. Fair Value Measurements

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

- Level 1 – Inputs are quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2 – Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transaction (less active markets).
- Level 3 – Inputs are unobservable estimates that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and marketable securities. At March 31, 2014 and June 30, 2013, substantially all of the Company's interest-bearing cash equivalent balances were concentrated in one institutional money market fund that has investments consisting primarily of certificates of deposit, commercial paper, time deposits, U.S. government agencies, treasury bills and treasury repurchase agreements. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

The Company's cash equivalents and marketable securities are classified within Level 1 or Level 2 on the basis of valuations using quoted market prices or alternative pricing sources and models utilizing market observable inputs, respectively. Certain of the Company's corporate debt securities were valued based on quoted prices for the specific securities in an active market and were therefore classified as Level 1. The remaining marketable securities have been valued on the basis of valuations provided by third-party pricing services, as derived from such services' pricing models. Inputs to the models may include, but are not limited to, reported trades, executable bid and ask prices, broker/dealer quotations, prices or yields of securities with similar characteristics, benchmark curves or information pertaining to the issuer, as well as industry and economic events. The pricing services may use a matrix approach, which considers information regarding securities with similar characteristics to determine the valuation for a security, and have been classified as Level 2. The following tables summarize the Company's assets carried at fair value measured on a recurring basis at March 31, 2014 and June 30, 2013 by valuation hierarchy (in thousands):

	March 31, 2014			
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 14,509	\$ 14,509	\$ —	\$ —
Marketable securities				
Corporate bonds	2,462	2,462	—	—
Commercial paper	250	—	250	—
	<u>\$ 17,221</u>	<u>\$ 16,971</u>	<u>\$ 250</u>	<u>\$ —</u>

[Table of Contents](#)

	June 30, 2013			
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 6,330	\$ 6,330	\$ —	\$ —
Marketable securities				
Corporate bonds	2,375	1,619	756	—
Commercial paper	999	—	999	—
	<u>\$ 9,704</u>	<u>\$ 7,949</u>	<u>\$ 1,755</u>	<u>\$ —</u>

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2014	June 30, 2013
Personnel costs	\$ 497	\$ 1,252
Professional fees	371	288
Clinical	261	353
Other	74	1
	<u>\$ 1,203</u>	<u>\$ 1,894</u>

7. Stockholders' Equity

In March 2014, the Company sold 1,700,000 shares of its common stock in a registered direct offering to a single institutional investor at a price of \$4.11 per share for gross proceeds of \$7.0 million. Placement agent fees and other share issue costs approximated \$186,000.

In December 2013, the Company entered into an at-the-market ("ATM") program pursuant to which the Company may, at its option, offer and sell shares of its common stock from time to time for an aggregate offering price of up to \$19.2 million. The Company pays the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. During the three and nine months ended March 31, 2014, the Company sold 57,770 and 381,562 common shares, respectively, for net proceeds of \$224,000 and \$1.5 million, respectively, reflecting a weighted-average gross selling price of \$3.98 per share. At March 31, 2014, an aggregate registered amount of approximately \$10.7 million of common stock remains available for sale under the Company's existing shelf registration statement.

In July 2013, the Company sold 3,494,550 shares of its common stock in an underwritten public offering at a price of \$3.10 per share for gross proceeds of \$10.8 million. Underwriting commissions and other share issue costs approximated \$890,000.

[Table of Contents](#)

In August 2012, the Company sold 2,494,419 shares of its common stock and warrants to purchase 623,605 shares of its common stock in a registered direct offering to institutional investors for gross proceeds of \$5.4 million. The shares and warrants were sold in units, each unit consisting of one share together with 0.25 of one warrant, at a negotiated price of \$2.15 per unit. Each whole warrant has an exercise price of \$2.50 per share and a five-year term, and became exercisable in February 2013. Placement agent fees and other share issue costs approximated \$700,000.

Warrants to Purchase Common Shares

The following table provides a reconciliation of US\$ warrants to purchase common stock for the nine months ended March 31, 2014 and 2013:

	Nine Months Ended March 31,			
	2014		2013	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	1,176,105	\$ 3.67	2,064,710	\$ 6.17
Issued	—	—	623,605	2.50
Expired	—	—	(1,512,210)	6.60
Balance and exercisable at end of period	<u>1,176,105</u>	<u>\$ 3.67</u>	<u>1,176,105</u>	<u>\$ 3.67</u>

At March 31, 2014, the remaining term of these warrants ranged from 1.8 to 3.4 years, representing a weighted average period of 2.6 years.

In addition, warrants to purchase 205,479 shares denominated in A\$ expired unexercised in July 2012.

Incentive Plans

The Company's 2008 Incentive Plan (the "2008 Plan") provides for the issuance of stock options and other stock awards to directors, employees and consultants. At March 31, 2014, a total of 5,591,255 shares of common stock were authorized for issuance under the 2008 Plan, of which 1,095,784 were available for issuance. The following table provides a reconciliation of stock option activity under the 2008 Plan for the nine months ended March 31, 2014:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2013	3,554,549	\$ 2.92		
Granted	778,500	3.51		
Exercised	(371,485)	2.45		
Forfeited	(67,825)	3.68		
Outstanding at March 31, 2014	<u>3,893,739</u>	<u>\$ 3.07</u>	<u>6.67</u>	<u>\$ 4,492</u>
Outstanding at March 31, 2014 - vested or unvested and expected to vest	<u>3,821,239</u>	<u>\$ 3.07</u>	<u>6.63</u>	<u>\$ 4,435</u>
Exercisable at March 31, 2014	<u>2,555,881</u>	<u>\$ 2.88</u>	<u>5.64</u>	<u>\$ 3,439</u>

Option grants for the nine months ended March 31, 2014 consisted of 613,500 options to employees with ratable annual vesting over 4 years and 165,000 options to non-executive directors with 1-year cliff vesting. The weighted-average grant date fair value of these option grants was \$2.48 per share. A total of 526,756 options vested

[Table of Contents](#)

during the nine months ended March 31, 2014. All option grants have a 10-year contractual life. In determining the grant date fair value of options, the Company uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of options awarded during the nine months ended March 31, 2014 based on the following key assumptions:

Option life (in years)	5.50 - 6.25
Stock volatility	94% - 96%
Risk-free interest rate	1.70% - 1.99%
Expected dividends	0%

In addition, during the three months ended September 30, 2012, the last remaining 112,500 options outstanding under an earlier incentive plan expired unexercised.

Stock-Based Compensation Expense

The Company's statements of comprehensive loss included total compensation expense from stock-based payment awards for the three and nine months ended March 31, 2014 and 2013, as follows (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2014	2013	2014	2013
Compensation expense included in:				
Research and development	\$ 142	\$ 116	\$ 373	\$ 422
General and administrative	299	196	590	496
	<u>\$ 441</u>	<u>\$ 312</u>	<u>\$ 963</u>	<u>\$ 918</u>

At March 31, 2014, there was approximately \$1.5 million of unrecognized compensation expense related to unvested options under the 2008 Plan, which is expected to be recognized as expense over a weighted average period of approximately 1.6 years.

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 an income tax benefit of \$31,000 and \$87,000 for the three and nine months ended March 31, 2014, respectively, as well as \$15,000 and \$85,000 for the three and nine months ended March 31, 2013, respectively. These income tax benefits related to earned foreign research and development tax credits.

For the three and nine months ended March 31, 2014 and 2013, the Company had no significant unrecognized tax benefits. At March 31, 2014 and June 30, 2013, the Company had no accrued penalties or interest related to uncertain tax positions.

9. Commitments and Contingencies

On March 21, 2014, the Company commenced a lease for approximately 13,650 square feet of combined office and laboratory space in Watertown, Massachusetts to replace the Company's previous lease that expired on April 5, 2014. The Company provided a cash-collateralized \$150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease. The initial lease term extends through April 2019, with a five-year renewal option at market rates.

[Table of Contents](#)

Minimum lease payments during the initial lease term are as follows (in thousands):

<u>Fiscal Year:</u>	
2014	\$ 73
2015	378
2016	392
2017	405
2018	419
Thereafter	358
	<u>\$2,025</u>

In addition, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts.

At March 31, 2014, the Company was subject to various routine legal proceedings and claims incidental to its business, which management believes will not have a material effect on the Company's financial position, results of operations or cash flows.

10. Loss Per Share

Basic net loss per share was computed by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share was computed by dividing the net loss by the sum of (i) the weighted average number of common shares outstanding and (ii) the weighted average number of common shares that would be issued on the exercise of all dilutive securities outstanding. Potentially dilutive shares were not included in the calculation of diluted net loss per share for each of the three and nine-month periods ended March 31, 2014 and 2013 as their inclusion would be anti-dilutive.

Potentially dilutive shares at March 31, 2014 and 2013 were as follows:

	<u>March 31,</u>	
	<u>2014</u>	<u>2013</u>
Options	3,893,739	3,670,115
Warrants	1,176,105	1,176,105
	<u>5,069,844</u>	<u>4,846,220</u>

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 and are not statements of 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, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: uncertainties with respect to: the number of clinical trials necessary to support an NDA for Medidur; Alimera’s ability to finance, achieve additional marketing approvals, obtain adequate pricing and reimbursement for, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for chronic DME in the EU; Alimera’s ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for chronic DME in the U.S.; our ability to finance, complete and achieve a successful outcome for Phase III trials for, and file and achieve marketing approvals for, Medidur for posterior uveitis, including achieving acceptable risk-to-benefit and safety profiles in light of the CRL for ILUVIEN; initiation, financing and success of Latanoprost Product Phase II trials and any exercise by Pfizer of its option; ability of Tethadur to deliver proteins, peptides and other large biologic molecules successfully and development of product candidates using the technology; ability to develop product candidates and products and potential related collaborations; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; continued sales of Retisert; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty income; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the SEC. 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 products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Using our core technology platforms, Durasert and BioSilicon, we are focused on treatment of chronic diseases of the back of the eye and are also exploring applications outside ophthalmology. We have developed three of the four sustained-release products for treatment of retinal diseases that have been approved in the U.S. or EU, and our lead development product began a Phase III clinical trial in the quarter ended June 2013. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaborations and license agreements.

[Table of Contents](#)

Medidur, our lead development product, is an injectable, sustained-release micro-insert designed to provide treatment of posterior uveitis over a period of up to three years. Medidur uses the same Durasert micro-insert and delivers the same dose of the same drug as ILUVIEN, which is a lower dose of the same drug as our FDA-approved Retisert for posterior uveitis. In the quarter ended June 2013, we commenced a Phase III clinical trial of Medidur. We originally planned to request U.S. Food and Drug Administration (“FDA”) approval of Medidur on the basis of two Phase III trials, but now plan to seek FDA approval based on data from the currently ongoing Phase III trial, combined with clinical data about our proprietary inserter, if ILUVIEN is approved by the FDA. We plan to have a confirmatory meeting with the FDA with respect to our regulatory strategy as more data become available. If ILUVIEN is not approved by the FDA, we plan to file for FDA approval as originally planned. We are developing Medidur independently.

ILUVIEN, our lead licensed product, is an injectable, sustained-release micro-insert that provides treatment over a period of up to three years of vision impairment associated with chronic DME. ILUVIEN is licensed to Alimera, and we are entitled to 20% of the net profits (as defined) from Alimera’s sales of ILUVIEN measured on a quarter-by-quarter and country-by-country basis. Alimera may recover 20% of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country, but only by an offset of up to 4% of the net profits earned in that country each quarter, reducing the Company’s net profit share to 16% in each country until those net losses are recouped.

Alimera launched ILUVIEN to serve patients with chronic DME considered insufficiently responsive to available therapies in the U.K. in April 2013 and in Germany in May 2013. In November 2013, the U.K.’s National Institute for Health and Care Excellence (“NICE”) recommended ILUVIEN as a treatment option for pseudophakic eyes (those that have had cataract surgery), subject to a simple patient access scheme, resulting in U.K. National Health Service (“NHS”) reimbursement for these patients, and in January 2014 Alimera commenced shipments of initial orders for ILUVIEN for chronic DME to U.K. NHS facilities. Previously, ILUVIEN for chronic DME was available only for private pay and privately insured patients in the U.K. In February 2014, the Scottish Medicines Consortium (SMC) accepted ILUVIEN for use within NHS Scotland under a similar patient access scheme for pseudophakic eyes.

Alimera intends to launch in France in 2014, where patients will be reimbursed for 100% of the cost of ILUVIEN under the Affection de Longue Durée, a specific program for severe chronic diseases such as diabetes.

ILUVIEN has also received marketing authorization in Austria, Portugal and Spain, and has been recommended for marketing authorization in Italy. In addition, Alimera has filed for ten additional EU country approvals through the Mutual Recognition Procedure.

In April 2014, Alimera entered into an exclusive agreement with Specialized Therapeutics Australia (“STA”) for the distribution of ILUVIEN in Australia and New Zealand. STA is responsible for regulatory and commercial matters, including marketing approval and reimbursement, in those countries. The agreement between Alimera and STA includes a milestone payment to Alimera upon achievement of a public reimbursement listing, and royalties based on net sales that will increase if a sales target is met. pSivida is entitled to 20% of any royalties and 33% of all other payments received by Alimera, including any milestone payment.

Alimera resubmitted a New Drug Application (“NDA”) for ILUVIEN for chronic DME to the FDA in March 2014, and the FDA set a new Prescription Drug User Fee Act (“PDUFA”) goal date of September 26, 2014. The NDA responded to questions raised in an October 2013 third Complete Response Letter (“CRL”) from the FDA, which identified concerns regarding the benefit to risk and safety profiles of ILUVIEN for chronic DME, and stated that the NDA could not be approved in its then present form. The NDA also provided data from ILUVIEN patients and from physician experience with ILUVIEN’s applicator in Germany and the U.K., and addressed deficiencies in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. In April 2014, the FDA accepted the NDA resubmission as a complete class 2 response to the CRL. FDA approval of ILUVIEN for DME would entitle us to a \$25.0 million milestone payment. Alimera entered into a loan agreement that provides for a \$25.0 million advance upon FDA approval on or prior to October 31, 2014 and certain other conditions to fund the milestone payment.

Our FDA-approved product Retisert provides sustained release treatment of posterior uveitis for approximately two and a half years and is licensed to and sold by Bausch & Lomb.

[Table of Contents](#)

We are engaged in pre-clinical research with respect to its BioSilicon and Durasert technology platforms. The primary focus of our BioSilicon research is the use of Tethadur for the sustained delivery of peptides, proteins, antibodies and other large biologic molecules in both ophthalmic and non-ophthalmic applications. Our research program also includes the use of Durasert technology in orthopedic applications and for systemic delivery of therapeutic agents.

We are also developing the Latanoprost Product to treat glaucoma and ocular hypertension. Under an amended collaboration agreement, Pfizer has an option, under certain circumstances, to license the development and commercialization of the Latanoprost Product worldwide.

Durasert™, Medidur™, BioSilicon™ and Tethadur™ are our trademarks, Retisert® is Bausch & Lomb's trademark, and ILUVIEN® and FAME™ are Alimera's trademarks.

All information in this Form 10-Q with respect to ILUVIEN, including regulatory and marketing information, and Alimera's plans and intentions, reflects information reported by Alimera.

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, 2013 ("fiscal year 2013"), we set forth our critical accounting policies and estimates, which included revenue recognition and valuation of our intangible assets. There have been no material changes to our critical accounting policies from the information provided in our Annual Report on Form 10-K for fiscal year 2013, with the exception of the following:

Recognition of Expense in Outsourced Clinical Trial Agreements

We recognize research and development expense with respect to outsourced agreements for clinical trials as the services are provided based on our assessment of the services performed. We have agreements with two contract research organizations ("CRO") to conduct a Phase III clinical trial of Medidur for posterior uveitis. We were contractually obligated for up to approximately \$10.1 million for services under these agreements as of March 31, 2014. The timing of actual amounts owed under the agreements will depend on various factors, including patient enrollment and other progress of the clinical trial. Differences between the amounts paid and our estimate of the work completed are recorded as a prepaid asset or accrued liability. We make our assessments of the services performed based on various factors, including evaluation by the third-party CRO and our own internal review of the work performed during the period, measurements of progress by us or by the third-party provider, data analysis with respect to work completed and our management's judgment. During the three and nine months ended March 31, 2014, we recognized approximately \$810,000 and \$3.2 million, respectively, of research and development expense attributable to the Medidur for posterior uveitis clinical trial. Changes in our estimates or differences between the actual level of services performed and our estimates may result in changes to our research and development expenses in future periods.

Results of Operations**Three Months Ended March 31, 2014 Compared to Three Months Ended March 31, 2013:**

	Three Months Ended March 31,		Change	
	2014	2013	Amounts	%
	(In thousands except percentages)			
Revenues	\$ 1,992	\$ 513	\$ 1,479	288%
Operating expenses:				
Research and development	2,269	1,587	682	43%
General and administrative	1,946	1,738	208	12%
Gain on sale of property and equipment	(4)	—	(4)	na
Total operating expenses	4,211	3,325	886	27%
Loss from operations	(2,219)	(2,812)	593	21%
Interest income	1	3	(2)	(67)%
Loss before income taxes	(2,218)	(2,809)	591	21%
Income tax benefit	31	15	16	107%
Net loss	<u>\$ (2,187)</u>	<u>\$ (2,794)</u>	<u>\$ 607</u>	<u>22%</u>

Revenues

Total revenues increased by \$1.5 million, or 288%, to \$2.0 million for the three months ended March 31, 2014 from \$513,000 for the three months ended March 31, 2013. This increase was primarily attributable to the recognition of \$1.5 million of contingent consideration under a completed feasibility study agreement for the Durasert technology platform.

We are entitled to share in net profits, on a country-by-country basis, from sales by Alimera of ILUVIEN, which was launched for chronic DME in the U.K and Germany in April 2013 and May 2013, respectively, and Alimera has reported that it plans to launch in France in 2014. We do not know when and if we will receive net profits payments with respect to each country where Alimera sells ILUVIEN. We will be entitled to a milestone payment of \$25.0 million from Alimera if the FDA approves ILUVIEN. The new PDUFA goal date for ILUVIEN is September 26, 2014.

Research and Development

Research and development increased by \$682,000, or 43%, to \$2.3 million for the three months ended March 31, 2014 from \$1.6 million for the three months ended March 31, 2013, reflecting approximately \$810,000 of CRO costs incurred in the fiscal 2014 third quarter for the Phase III clinical trials of Medidur for posterior uveitis, which commenced in the quarter ended June 30, 2013, partially offset by lower personnel costs. We expect to continue to incur significant research and development expense for Medidur during the remainder of fiscal year 2014 and in future periods until conclusion of Medidur clinical development.

General and Administrative

General and administrative increased by \$208,000, or 12%, to \$1.9 million for the three months ended March 31, 2014 from \$1.7 million for the three months ended March 31, 2013, and was primarily attributable to higher professional fees and stock-based compensation.

[Table of Contents](#)**Income Tax Benefit**

Income tax benefit was \$31,000 for the three months ended March 31, 2014 compared to \$15,000 for the quarter a year earlier, and consisted of refundable foreign research and development tax credits.

Nine Months Ended March 31, 2014 Compared to Nine Months Ended March 31, 2013:

	Nine Months Ended March 31,		Change	
	2014	2013	Amounts	%
	(In thousands except percentages)			
Revenues	\$ 3,181	\$ 1,651	\$ 1,530	93%
Operating expenses:				
Research and development	7,267	4,685	2,582	55%
General and administrative	5,468	5,016	452	9%
Gain on sale of property and equipment	(76)	—	(76)	na
Total operating expenses	12,659	9,701	2,958	30%
Loss from operations	(9,478)	(8,050)	(1,428)	(18)%
Other income (expense):				
Interest income	3	14	(11)	(79)%
Other expense, net	—	(2)	2	na
Total other income	3	12	(9)	(75)%
Loss before income taxes	(9,475)	(8,038)	(1,437)	(18)%
Income tax benefit	87	85	2	2%
Net loss	<u>\$ (9,388)</u>	<u>\$ (7,953)</u>	<u>\$ (1,435)</u>	<u>(18)%</u>

Revenues

Revenues increased by \$1.5 million, or 93%, to \$3.2 million for the nine months ended March 31, 2014 from approximately \$1.7 million for the nine months ended March 31, 2013. The increase was primarily attributable to the recognition of \$1.5 million of contingent consideration under a completed feasibility study agreement.

Research and Development

Research and development increased by \$2.6 million, or 55%, to \$7.3 million for the nine months ended March 31, 2014 from \$4.7 million for the nine months ended March 31, 2013. A \$3.0 million net increase in pre-clinical and clinical development costs, predominantly CRO costs incurred in the first nine months of fiscal 2014 for the Phase III clinical trial of Medidur for posterior uveitis, was partially offset by lower personnel costs.

General and Administrative

General and administrative increased by \$452,000, or 9%, to \$5.5 million for the nine months ended March 31, 2014 from \$5.0 million for the nine months ended March 31, 2013, primarily attributable to higher professional fees and stock-based compensation.

Gain on Sale of Property and Equipment

During the nine months ended March 31, 2014, fully depreciated property and equipment no longer in use were sold for \$76,000 resulting in a gain.

Income Tax Benefit

Income tax benefit totaled \$87,000 for the nine months ended March 31, 2014 compared to \$85,000 for the nine months ended March 31, 2013, and consisted of refundable foreign research and development tax credits.

Liquidity and Capital Resources

During the past three fiscal years and the first three quarters of the current fiscal year, we financed our operations primarily from sales of equity securities, as well as operating cash flows from license fees, research and development funding and royalty income from our collaboration partners. At March 31, 2014, our principal source of liquidity was cash, cash equivalents and marketable securities totaling \$21.3 million.

With the exception of net income in fiscal year 2010 resulting from a non-recurring event, we have incurred operating losses each year since inception, and at March 31, 2014, we had a total accumulated deficit of \$273.0 million. We do not currently have any assured sources of revenue, and we generally expect negative cash flows from operations on a quarterly basis unless and until such time as we receive sufficient revenues from ILUVIEN or one or more of our other product candidates achieve regulatory approval and provide us sufficient revenues. We believe that our capital resources of \$21.3 million at March 31, 2014, together with expected cash inflows under existing collaboration agreements, will enable us to fund our current and planned operations through the third quarter of calendar year 2015. This estimate includes expected costs of clinical development of Medidur, but excludes any potential milestone or net profits receipts under our Alimera collaboration agreement. Our ability to fund our planned operations beyond then, including completion of clinical development of Medidur, is expected to depend on the amount and timing of cash receipts under our Alimera collaboration agreement, as well as proceeds from any future collaboration or other agreements and/or financing transactions.

Whether we will require, or desire, to raise additional capital will be influenced by many factors, including, but not limited to:

- whether and when we receive a \$25.0 million milestone payment from Alimera that would be due if ILUVIEN is approved by the FDA;
- whether, when and to what extent we receive other revenues from Alimera with respect to commercialization of ILUVIEN;
- the timing and cost of development of Medidur for posterior uveitis;
- whether and when we initiate Phase II clinical trials for the Latanoprost Product and Pfizer exercises its option;
- whether and to what extent we internally fund, when we initiate, and how we conduct product development programs, including with respect to BioSilicon and Tethadur applications;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan resulting in increases or decreases in our need for capital.

Management currently believes that extending our cash position beyond the third quarter of calendar year 2015 depends significantly on possible cash flows from an FDA approval of ILUVIEN and the successful commercialization by Alimera of ILUVIEN for chronic DME. However, there is no assurance that ILUVIEN for chronic DME will be approved by the FDA, achieve market acceptance in any country in the EU, or, if approved, in the U.S., or that we will receive significant, if any, revenues from ILUVIEN for chronic DME.

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. Although we may be able to sell common shares with an aggregate offering price of up to \$10.7 million under our existing ATM facility as of March 31, 2014, we do not know whether and to what extent we will seek to sell shares pursuant to that program and, if we

[Table of Contents](#)

are able to do so, on what terms. The state of the economy and the financial and credit markets at the time or times we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may be required to delay, reduce the scope of or eliminate research or development programs, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

Our consolidated statements of historical cash flows are summarized as follows (in thousands):

	Nine Months Ended		
	March 31,		Change
	2014	2013	
Net loss:	\$ (9,388)	\$ (7,953)	\$ (1,435)
Changes in operating assets and liabilities	(96)	801	(897)
Other adjustments to reconcile net loss to cash flows from operating activities	1,598	1,787	(189)
Net cash used in operating activities	<u>\$ (7,886)</u>	<u>\$ (5,365)</u>	<u>\$ (2,521)</u>
Net cash provided by investing activities	<u>\$ 487</u>	<u>\$ 4,077</u>	<u>\$ (3,590)</u>
Net cash provided by financing activities	<u>\$19,058</u>	<u>\$ 4,669</u>	<u>\$14,389</u>

Net cash used in operating activities increased by \$2.5 million on a comparative basis, represented by an approximate \$3.8 million increase in operating cash outflows, partially offset by a \$1.2 million increase of collaborative research and development and royalty cash inflows. Higher operating cash outflows consisted primarily of (i) approximately \$2.2 million of CRO payments associated with the Medidur Phase III trial; (ii) approximately \$1.1 million of incentive compensation awards, reflecting awards for fiscal 2013 and also for fiscal 2012 as a result of performance conditions achieved during fiscal 2013; and (iii) an approximate \$300,000 increase in professional fees.

Net cash provided by investing activities consisted principally of \$636,000 of maturities, net of purchases, of marketable securities during the nine months ended March 31, 2014 compared to approximately \$4.1 million of maturities, net of purchases, of marketable securities during the nine months ended March 31, 2013.

Net cash provided by financing activities for the nine months ended March 31, 2014 consisted of \$16.7 million of aggregate net proceeds from a March 2014 registered direct offering and a July 2013 underwritten public offering of common shares, \$1.5 million of net proceeds from sales of common shares under our ATM facility and \$909,000 of proceeds from the exercise of stock options. This compared to \$4.7 million of net proceeds from an August 2012 registered direct offering of common shares and warrants.

We had no borrowings or line of credit facilities as of March 31, 2014.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of March 31, 2014 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

Foreign Currency Exchange Rates

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations, and the Pound Sterling is the functional currency for our U.K. operations. Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling impact the net operating expenses of our U.K. operations. The weakening of the U.S. dollar during the three months ended March 31, 2014

[Table of Contents](#)

compared to the prior year's quarter resulted in a net increase in research and development expenses of \$30,000. For every incremental 5% strengthening or weakening of the weighted average exchange rate of the U.S. dollar in relation to the Pound Sterling, our research and development expense for the three months ended March 31, 2014 would have decreased or increased by \$24,000, respectively. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of comprehensive loss exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the Pound Sterling to the U.S. dollar also impacted total stockholders' equity. As reported in the statement of comprehensive loss, the relative weakening of the U.S. dollar in relation to the Pound Sterling at March 31, 2014 compared to June 30, 2013 resulted in \$100,000 of other comprehensive income for the nine months ended March 31, 2014 due to the translation of £750,000 of net assets of our U.K. operations, predominantly the BioSilicon technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at March 31, 2014 in relation to the Pound Sterling, our stockholders' equity at March 31, 2014 would have decreased or increased, respectively, by \$62,000.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2014. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2014, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II: OTHER INFORMATION

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in Part I, "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended June 30, 2013.

Item 6. Exhibits

- 31.1 Certification of Principal Executive Officer required by Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer required by Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101 The following materials from pSivida Corp.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Comprehensive Loss; (iii) Condensed Consolidated Statement of Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements

SIGNATURES

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

Date: May 14, 2014

pSivida Corp.

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: May 14, 2014

/s/ Paul Ashton

Name: Paul Ashton

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

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

I, Leonard S. Ross, certify that:

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

Date: May 14, 2014

/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 March 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Ashton, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2014

/s/ Paul Ashton

Name: Paul Ashton

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

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

In connection with the Quarterly Report of pSivida Corp. (the "Company") on Form 10-Q for the quarter ended March 31, 2014, 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: May 14, 2014

/s/ Leonard S. Ross

Name: Leonard S. Ross

Title: Vice President, Finance
(Principal Financial Officer)