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

FORM 10-Q

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

For the quarterly period ended December 31, 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 29,412,365 shares of the registrant’s common stock, \$0.001 par value, outstanding as of February 3, 2015.

[Table of Contents](#)

PSIVIDA CORP. AND SUBSIDIARIES
INDEX TO FORM 10-Q

	Page
<u>PART I: FINANCIAL INFORMATION</u>	
Item 1. <u>Unaudited Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets – December 31, 2014 and June 30, 2014</u>	3
<u>Condensed Consolidated Statements of Comprehensive (Loss) Income – Three and Six Months Ended December 31, 2014 and 2013</u>	4
<u>Condensed Consolidated Statement of Stockholders' Equity – Six Months Ended December 31, 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows – Six Months Ended December 31, 2014 and 2013</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	21
Item 4. <u>Controls and Procedures</u>	22
<u>PART II: OTHER INFORMATION</u>	
Item 1A. <u>Risk Factors</u>	22
Item 6. <u>Exhibits</u>	22
<u>Signatures</u>	23
<u>Certifications</u>	

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, 2014	June 30, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 29,751	\$ 15,334
Marketable securities	5,935	2,944
Accounts and other receivables	727	517
Prepaid expenses and other current assets	935	547
Total current assets	37,348	19,342
Property and equipment, net	265	297
Intangible assets, net	2,301	2,765
Other assets	116	117
Restricted cash	150	150
Total assets	\$ 40,180	\$ 22,671
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 384	\$ 464
Accrued expenses	1,820	1,524
Deferred revenue	69	138
Total current liabilities	2,273	2,126
Deferred revenue	5,584	5,584
Deferred rent	48	37
Total liabilities	7,905	7,747
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, 29,412,365 and 29,298,558 shares issued and outstanding at December 31, 2014 and June 30, 2014, respectively	29	29
Additional paid-in capital	291,825	290,864
Accumulated deficit	(260,522)	(277,013)
Accumulated other comprehensive income	943	1,044
Total stockholders' equity	32,275	14,924
Total liabilities and stockholders' equity	\$ 40,180	\$ 22,671

See notes to condensed consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(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>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
Collaborative research and development	\$ 164	\$ 300	\$25,245	\$ 473
Royalty income	357	292	583	716
Total revenues	<u>521</u>	<u>592</u>	<u>25,828</u>	<u>1,189</u>
Operating expenses:				
Research and development	2,767	2,494	5,551	4,998
General and administrative	1,870	1,711	3,604	3,522
Gain on sale of property and equipment	—	(72)	—	(72)
Total operating expenses	<u>4,637</u>	<u>4,133</u>	<u>9,155</u>	<u>8,448</u>
(Loss) income from operations	(4,116)	(3,541)	16,673	(7,259)
Interest income	3	1	6	2
(Loss) income before income taxes	(4,113)	(3,540)	16,679	(7,257)
Income tax benefit (expense)	38	26	(188)	56
Net (loss) income	<u>\$ (4,075)</u>	<u>\$ (3,514)</u>	<u>\$16,491</u>	<u>\$ (7,201)</u>
Net (loss) income per common share:				
Basic	<u>\$ (0.14)</u>	<u>\$ (0.13)</u>	<u>\$ 0.56</u>	<u>\$ (0.27)</u>
Diluted	<u>\$ (0.14)</u>	<u>\$ (0.13)</u>	<u>\$ 0.54</u>	<u>\$ (0.27)</u>
Weighted average common shares:				
Basic	<u>29,367</u>	<u>26,953</u>	<u>29,345</u>	<u>26,435</u>
Diluted	<u>29,367</u>	<u>26,953</u>	<u>30,618</u>	<u>26,435</u>
Net (loss) income	<u>\$ (4,075)</u>	<u>\$ (3,514)</u>	<u>\$16,491</u>	<u>\$ (7,201)</u>
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(46)	30	(96)	95
Net unrealized loss on marketable securities	(2)	—	(5)	—
Other comprehensive (loss) income	<u>(48)</u>	<u>30</u>	<u>(101)</u>	<u>95</u>
Comprehensive (loss) income	<u>\$ (4,123)</u>	<u>\$ (3,484)</u>	<u>\$16,390</u>	<u>\$ (7,106)</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, 2014	29,298,558	\$ 29	\$290,864	\$ (277,013)	\$ 1,044	\$ 14,924
Net income	—	—	—	16,491	—	16,491
Other comprehensive loss	—	—	—	—	(101)	(101)
Exercise of stock options	113,807	—	235	—	—	235
Stock-based compensation	—	—	726	—	—	726
Balance at December 31, 2014	<u>29,412,365</u>	<u>\$ 29</u>	<u>\$291,825</u>	<u>\$ (260,522)</u>	<u>\$ 943</u>	<u>\$ 32,275</u>

See notes to condensed consolidated financial statements

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

	Six Months Ended	
	December 31,	
	2014	2013
Cash flows from operating activities:		
Net income (loss)	\$16,491	\$ (7,201)
Adjustments to reconcile net income (loss) to cash flows from operating activities:		
Amortization of intangible assets	389	386
Depreciation of property and equipment	57	68
Stock-based compensation expense	726	522
Amortization of bond premium on marketable securities	41	24
Gain on sale of property and equipment	—	(72)
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(618)	697
Accounts payable and accrued expenses	230	(1,308)
Deferred revenue	(69)	850
Deferred rent	10	—
Net cash provided by (used in) operating activities	<u>17,257</u>	<u>(6,034)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(3,287)	—
Maturities of marketable securities	250	2,850
Purchases of property and equipment	(28)	(21)
Proceeds from sale of property and equipment	—	72
Change in restricted cash	—	(150)
Net cash (used in) provided by investing activities	<u>(3,065)</u>	<u>2,751</u>
Cash flows from financing activities:		
Proceeds from issuance of stock, net of issuance costs	—	11,144
Exercise of stock options	235	457
Net cash provided by financing activities	<u>235</u>	<u>11,601</u>
Effect of foreign exchange rate changes on cash and cash equivalents	(10)	2
Net increase in cash and cash equivalents	14,417	8,320
Cash and cash equivalents at beginning of period	15,334	6,899
Cash and cash equivalents at end of period	<u>\$29,751</u>	<u>\$15,219</u>
Supplemental disclosure of non-cash financing activities:		
Stock issuance costs	—	118

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 December 31, 2014 and for the three and six months ended December 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, 2014. 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, 2014, 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) income 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, 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 Tethadur™, the Company is focused on treatment of chronic diseases of the back of the eye and is also exploring applications outside ophthalmology. The Company’s lead product candidate Medidur™ is in a pivotal Phase III clinical trial, its lead licensed product ILUVIEN® was recently approved by the U.S. Food and Drug Administration (“FDA”) in the U.S. and was previously approved in the European Union (“EU”), and the Company’s pipeline includes potential product candidates at earlier stages of development. The Company’s Durasert technology is the basis of three of the four sustained-release products for treatment of retinal diseases currently approved in the U.S. or EU. The Company’s strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

Medidur is an injectable, sustained-release micro-insert designed to treat chronic non-infectious uveitis affecting the posterior of the eye (“posterior uveitis”) over a period of up to three years. Medidur uses the same Durasert micro-insert used in ILUVIEN (same design, same drug, same polymers, same release rate) and delivers a lower dose of the same drug as the Company’s FDA-approved Retisert® for posterior uveitis, which is licensed to Bausch & Lomb. The Company expects to seek FDA approval based on safety and efficacy data from its single ongoing Phase III trial, with supplemental clinical data on the safety and usability of its proprietary inserter. The Company plans to have a confirmatory meeting on its regulatory strategy with the FDA, and it is possible that the FDA could require a second Phase III trial. The Company is developing Medidur independently.

ILUVIEN®, the Company’s most recently approved product, is an injectable, sustained-release micro-insert that provides treatment of diabetic macular edema (“DME”) for up to three years from a single administration. ILUVIEN is licensed to and sold by Alimera Sciences, Inc. (“Alimera”), and the Company is entitled to a share of the net profits (as defined) from Alimera’s sales of ILUVIEN on a country-by-country, quarter-by-quarter basis.

On September 26, 2014, the FDA approved ILUVIEN for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. As a result, the Company earned a \$25.0 million milestone from Alimera, which was recorded as revenue in the quarter ended September 30, 2014 and received on October 24, 2014. ILUVIEN is expected to be commercially available in the U.S. during the first calendar quarter of 2015.

ILUVIEN has been commercially available in the United Kingdom (“U.K.”) and Germany since June 2013, and was launched in Portugal in January 2015, for the treatment of chronic DME considered insufficiently responsive to available therapies. ILUVIEN has marketing approvals in twelve other EU countries, with two EU approvals still pending.

[Table of Contents](#)

Alimera has exclusively sublicensed distribution, regulatory and reimbursement matters of ILUVIEN for DME in Australia and New Zealand. The Company is entitled to 20% of any royalties and 33% of all other payments received by Alimera, including any milestone payment.

The Company's pre-clinical research is primarily focused on developing products using its Tethadur and Durasert technology platforms. The Company is seeking to provide targeted and systemic sustained delivery of peptides, antibodies, other proteins and large biologic molecules for treatment of various conditions, and to provide sustained delivery of therapeutic agents to treat wet and dry age-related macular degeneration ("AMD"), osteoarthritis and glaucoma.

The Company has a history of operating losses and has financed its operations primarily from the receipt of license fees, milestone payments, research and development funding and royalty income from its collaboration partners and from proceeds of sales of its equity securities. The Company believes that its cash, cash equivalents and marketable securities of \$35.7 million at December 31, 2014 will enable the Company to maintain its current and planned operations into calendar year 2017. This estimate excludes any potential net profits receipts from sales of ILUVIEN.

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 recently issued and adopted pronouncements will not have a material impact on the Company's financial position, results of operations and cash flows or do not apply to the Company's operations.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP. ASU 2014-09 will become effective on July 1, 2017, and early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the impact this standard will have on its financial statements.

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. In September 2014, the Company earned a \$25.0 million milestone from Alimera as a result of the FDA approval of ILUVIEN, which was recorded as revenue in the quarter ended September 30, 2014 and received in October 2014. 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 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.

The Company's performance obligations ended on December 31, 2009 and, accordingly, all 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 \$26,000 and \$35,000 for the three months ended December 31, 2014 and 2013, respectively, and \$25.1 million and \$48,000 for the six months ended December 31, 2014 and 2013, respectively. In addition to the FDA milestone, these revenues consisted principally 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

[Table of Contents](#)

bioerodible micro-insert designed to deliver latanoprost for human ophthalmic disease or conditions other than uveitis (the "Latanoprost Product"). Pfizer made an upfront payment of \$2.3 million and the Company agreed to use commercially reasonable efforts to fund the development for at least one year, including assumption of an investigator-sponsored Phase I/II dose-escalation study. The Company may, at its option, conduct Phase II clinical trials, which have not been initiated, for the purpose of demonstrating Proof-of-Concept ("POC"). If the Company were to issue a final report demonstrating POC, Pfizer would have a 90-day exercise option for an exclusive, worldwide license to develop and commercialize the Latanoprost Product in return for a \$20.0 million payment and potential double-digit sales-based royalties and prescribed development, regulatory and sales performance milestone payments. If the Company elects to cease development of the Latanoprost Product prior to POC, Pfizer could exercise its option for the same worldwide license upon payment of a lesser option fee, with comparable reductions in any future milestones and royalties. If Pfizer does not exercise its option when available, the Restated Pfizer Agreement will automatically terminate, with any remaining deferred revenue balance recorded as revenue at that time, provided, however, that the Company would retain the right to develop and commercialize the Latanoprost Product.

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 using the proportional performance method. The Company recorded no revenue and \$25,000 for the three months ended December 31, 2014 and 2013, respectively, and no revenue and \$56,000 for the six months ended December 31, 2014 and 2013, respectively. As of December 31, 2014, the Company continues to evaluate the Latanoprost Product and, consequently, the Company cannot currently estimate the remaining performance period. As a result, total deferred revenue of approximately \$5.6 million at each of December 31, 2014 and June 30, 2014 was classified as noncurrent. Costs associated with developing the Latanoprost Product are reflected in operating expenses in the period in which they are incurred.

Pfizer owned approximately 6.3% of the Company's outstanding common stock at December 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 \$357,000 and \$292,000 for the three months ended December 31, 2014 and 2013, respectively, and \$583,000 and \$716,000 for the six months ended December 31, 2014 and 2013, respectively. Accounts receivable from Bausch & Lomb totaled \$362,000 at December 31, 2014 and \$302,000 at June 30, 2014.

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. 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, but only 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 \$100,000 for the three and six month periods ended December 31, 2014 and \$102,000 for the three and six month periods ended December 31, 2013. As of December 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

[Table of Contents](#)

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 \$35,000 and \$131,000 for the three months ended December 31, 2014 and 2013, respectively, and \$70,000 and \$260,000 for the six months ended December 31, 2014 and 2013, respectively.

3. Intangible Assets

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

	<u>Six Months Ended December 31, 2014</u>	<u>Year Ended June 30, 2014</u>
Patented technologies		
Gross carrying amount at beginning of period	\$ 41,689	\$ 38,941
Foreign currency translation adjustments	(2,259)	2,748
Gross carrying amount at end of period	39,430	41,689
Accumulated amortization at beginning of period	(38,924)	(35,511)
Amortization expense	(389)	(778)
Foreign currency translation adjustments	2,184	(2,635)
Accumulated amortization at end of period	(37,129)	(38,924)
Net book value at end of period	<u>\$ 2,301</u>	<u>\$ 2,765</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 \$193,000 and \$194,000 for the three months ended December 31, 2014 and 2013, respectively, and \$389,000 and \$386,000 for the six months ended December 31, 2014 and 2013, respectively. The carrying value of intangible assets at December 31, 2014 of \$2.3 million (approximately \$1.6 million attributable to the Durasert technology and \$0.7 million attributable to the BioSilicon™ technology (including Tethadur)) is expected to be amortized on a straight-line basis over the remaining estimated useful life of 3.0 years, or approximately \$767,000 per year.

4. Marketable Securities

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

	<u>December 31, 2014</u>		
	<u>Amortized Cost</u>	<u>Unrealized Loss</u>	<u>Fair Value</u>
Corporate bonds	\$ 5,691	\$ (6)	\$ 5,685
Commercial paper	250	—	250
Total marketable securities	<u>\$ 5,941</u>	<u>\$ (6)</u>	<u>\$ 5,935</u>

	<u>June 30, 2014</u>		
	<u>Amortized</u>	<u>Unrealized</u>	
	<u>Cost</u>	<u>Loss</u>	<u>Fair Value</u>
Corporate bonds	\$ 2,446	\$ (1)	\$ 2,445
Commercial paper	499	—	499
Total marketable securities	<u>\$ 2,945</u>	<u>\$ (1)</u>	<u>\$ 2,944</u>

During the six months ended December 31, 2014, \$3.3 million of marketable securities were purchased and \$250,000 of such securities matured. At December 31, 2014, the marketable securities had maturities ranging from 15 days to 11 months, with a weighted average maturity of 5.1 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 December 31, 2014 and June 30, 2014, 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.

[Table of Contents](#)

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 December 31, 2014 and June 30, 2014 by valuation hierarchy (in thousands):

	December 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	\$ 20,957	\$ 20,957	\$ —	\$ —
Marketable securities				
Corporate bonds	5,685	2,270	3,415	—
Commercial paper	250	—	250	—
	<u>\$ 26,892</u>	<u>\$ 23,227</u>	<u>\$ 3,665</u>	<u>\$ —</u>

	June 30, 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	\$ 14,260	\$ 14,260	\$ —	\$ —
Marketable securities				
Corporate bonds	2,444	1,936	508	—
Commercial paper	500	—	500	—
	<u>\$ 17,204</u>	<u>\$ 16,196</u>	<u>\$ 1,008</u>	<u>\$ —</u>

6. Accrued Expenses

Accrued expenses consisted of the following at December 31, 2014 and June 30, 2014 (in thousands):

	December 31, 2014	June 30, 2014
Personnel costs	\$ 630	\$ 952
Professional fees	322	249
Clinical	829	316
Other	39	7
	<u>\$ 1,820</u>	<u>\$ 1,524</u>

7. Stockholders' Equity

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, representing the then remaining balance of the Company's shelf registration statement. In connection with execution of the ATM program, the Company incurred transaction costs of \$153,000. In addition, 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 six months ended December 31, 2014, the Company did not sell any shares under this program. During the three months ended December 31, 2013, the Company sold 323,792 common shares for net proceeds of approximately \$1.25 million.

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.

Warrants to Purchase Common Shares

During each of the six month periods ended December 31, 2014 and 2013, there were a total of 1,176,105 outstanding and exercisable warrants to purchase common shares at a weighted-average exercise price of \$3.67. At December 31, 2014, the remaining term of these warrants ranged from 1.1 to 2.6 years, representing a weighted average period of 1.9 years.

Incentive Plan

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 December 31, 2014, a total of 6,341,255 shares of common stock were authorized for issuance under the 2008 Plan, of which 1,080,817 were available for grant of future awards. Shares issuable under the 2008 Plan are subject to an annual increase pursuant to the terms of the plan. The following table provides a reconciliation of stock option activity under the 2008 Plan for the six months ended December 31, 2014:

	<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, 2014	3,791,001	\$ 3.08		
Granted	831,200	4.48		
Exercised	(113,807)	2.07		
Forfeited	(17,445)	3.88		
Outstanding at December 31, 2014	<u>4,490,949</u>	<u>\$ 3.36</u>	<u>6.67</u>	<u>\$ 4,122</u>
Outstanding at December 31, 2014 - vested or unvested and expected to vest	<u>4,407,364</u>	<u>\$ 3.35</u>	<u>6.63</u>	<u>\$ 4,085</u>
Exercisable at December 31, 2014	<u>2,911,157</u>	<u>\$ 3.04</u>	<u>5.51</u>	<u>\$ 3,472</u>

Option grants for the six months ended December 31, 2014 consisted of 701,200 options to employees with ratable annual vesting over 4 years, 90,000 options to non-executive directors with 1-year cliff vesting and 40,000 options to a newly appointed non-executive director with ratable annual vesting over 3 years. All option grants have a 10-year contractual life. The weighted-average grant date fair value of these option grants was \$3.33 per share. A total of 559,408 options vested during the six months ended December 31, 2014. 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 six months ended December 31, 2014 based on the following key assumptions:

Option life (in years)	5.50 - 6.25
Stock volatility	79% - 93%
Risk-free interest rate	1.71% - 2.00%
Expected dividends	0%

Stock-Based Compensation Expense

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

	<u>Three Months Ended December 31,</u>		<u>Six Months Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Compensation expense included in:				
Research and development	\$ 198	\$ 154	\$ 310	231
General and administrative	219	151	416	291
	<u>\$ 417</u>	<u>\$ 305</u>	<u>\$ 726</u>	<u>\$ 522</u>

[Table of Contents](#)

At December 31, 2014, there was approximately \$2.9 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 1.8 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 \$38,000 for the three months ended December 31, 2014 and an income tax expense of \$188,000 for the six months ended December 31, 2014. The Company recorded an income tax benefit of \$26,000 and \$56,000 for the three and six months ended December 31, 2013, respectively. The current year-to-date income tax expense predominantly reflects a \$260,000 federal alternative minimum tax payment based upon taxable income for the tax year ended December 31, 2014, which was primarily attributable to receipt of the \$25.0 million FDA approval milestone. The tax benefits in each period represented earned foreign research and development tax credits.

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

9. Commitments and Contingencies

The Company's lease for its U.S. office and laboratory space in Watertown, Massachusetts extends through April 2019, with a five-year renewal option at market rates. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts. The Company's obligations under the lease are secured by a cash-collateralized \$150,000 irrevocable standby letter of credit.

At December 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. Net (Loss) Income per Share

Basic net (loss) income per share is computed by dividing the net (loss) income by the weighted average number of common shares outstanding during the period. For periods in which the Company reports net income, diluted net income per share is determined by adding to the basic weighted average number of common shares outstanding the total number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive.

The following table reconciles the number of shares used to compute basic and diluted net (loss) income per share:

	<u>Three Months Ended December 31,</u>		<u>Six Months Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Number of common shares - basic	29,366,669	26,952,679	29,344,689	26,435,300
Effect of dilutive securities:				
Stock options	—	—	1,016,710	—
Warrants	—	—	256,745	—
Number of common shares - diluted	<u>29,366,669</u>	<u>26,952,679</u>	<u>30,618,144</u>	<u>26,435,300</u>

[Table of Contents](#)

Potential common stock equivalents excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive were as follows:

	<u>Three Months Ended December 31,</u>		<u>Six Months Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Options outstanding	4,490,949	4,111,949	1,823,824	3,670,115
Warrants outstanding	1,176,105	1,176,105	552,500	1,176,105
	<u>5,667,054</u>	<u>5,288,054</u>	<u>2,376,324</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: ability to achieve profitable operations and access to capital; fluctuations in operating results; further impairment of intangible assets; decline in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; number of clinical trials necessary to support an NDA for, and regulatory approval and successful commercialization, of Medidur; development of the Latanoprost Product and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver large biologic molecules and development of products using Tethadur; ability to successfully develop product candidates, complete clinical trials and receive regulatory approvals; ability to market and sell products; success of current and future license agreements; termination of license agreements; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; 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 make 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 Tethadur™, we are focused on treatment of chronic diseases of the back of the eye and are also exploring applications outside ophthalmology. Our lead product candidate Medidur™ is in a pivotal Phase III clinical trial, our lead licensed product ILUVIEN® was recently approved by the U.S. Food and Drug Administration (“FDA”) in the U.S. and was previously approved in the European Union (“EU”), and our pipeline includes potential product candidates at earlier stages of development. Our Durasert technology is the basis of three of the four sustained-release products for treatment of retinal diseases that have been approved in the U.S. or EU. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaborations and license agreements.

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 used in ILUVIEN (same design, same drug, same polymers, same release rate) and delivers a lower dose of the same drug as our FDA-approved Retisert® for posterior uveitis, which is licensed to Bausch & Lomb. We expect to seek FDA approval based on safety and efficacy data from our single ongoing Phase III trial, with supplemental clinical data

[Table of Contents](#)

on the safety and usability of our proprietary inserter. We plan to have a confirmatory meeting on our regulatory strategy with the FDA, and it is possible that the FDA could require a second Phase III trial. We are developing Medidur independently.

ILUVIEN, our most recently approved product, is an injectable, sustained-release micro-insert that provides treatment of diabetic macular edema (“DME”) for up to three years from a single administration. ILUVIEN is licensed to and sold by Alimera Sciences, Inc. (“Alimera”), and we are entitled to a share of the net profits (as defined) from Alimera’s sales of ILUVIEN on a country-by-country basis.

On September 26, 2014, the FDA approved ILUVIEN for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. As a result, we earned a \$25.0 million milestone from Alimera, which was recorded as revenue in the quarter ended September 30, 2014 and received on October 24, 2014. ILUVIEN is expected to be commercially available in the U.S. during the first calendar quarter of 2015.

ILUVIEN has been commercially available in the United Kingdom (“U.K.”) and Germany since June 2013, and was launched in Portugal in January 2015, for the treatment of chronic DME considered insufficiently responsive to available therapies. ILUVIEN has marketing approvals in twelve other EU countries, with two EU approvals still pending.

Alimera has exclusively sublicensed distribution, regulatory and reimbursement matters of ILUVIEN for DME in Australia and New Zealand. We are entitled to 20% of any royalties and 33% of all other payments received by Alimera, including any milestone payment.

Our pre-clinical research is primarily focused on developing products using our Tethadur and Durasert technology platforms. We are seeking to provide targeted and systemic sustained delivery of peptides, antibodies, other proteins and large biologic molecules for treatment of various conditions, and to provide sustained delivery of therapeutic agents to treat wet and dry age-related macular degeneration (“AMD”), osteoarthritis and glaucoma.

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

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, 2014 (“fiscal year 2014”), we set forth our critical accounting policies and estimates, which included revenue recognition, recognition of expense in outsourced clinical trial agreements and valuation of 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 2014.

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

	Three Months Ended December 31,		Change	
	2014	2013	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	\$ 164	\$ 300	\$ (136)	(45)%
Royalty income	357	292	65	22%
Total revenues	<u>521</u>	<u>592</u>	<u>(71)</u>	<u>(12)%</u>
Operating expenses:				
Research and development	2,767	2,494	273	11%
General and administrative	1,870	1,711	159	9%
Gain on sale of property and equipment	—	(72)	72	100%
Total operating expenses	<u>4,637</u>	<u>4,133</u>	<u>504</u>	<u>12%</u>
Loss from operations	(4,116)	(3,541)	(575)	(16)%
Interest income	3	1	2	200%
Loss before income taxes	(4,113)	(3,540)	(573)	(16)%
Income tax benefit	38	26	12	46%
Net loss	<u><u>\$ (4,075)</u></u>	<u><u>\$ (3,514)</u></u>	<u><u>\$ (561)</u></u>	<u><u>(16)%</u></u>

Revenues

Collaborative research and development revenues totaled \$164,000 for the three months ended December 31, 2014 compared to \$300,000 for the three months ended December 31, 2013. This decrease was primarily attributable to lower revenues related to technology evaluation agreements.

Royalty income increased by \$65,000, or 22%, to \$357,000 for the three months ended December 31, 2014 compared to \$292,000 for the three months ended December 31, 2013.

We are entitled to share in net profits, on a quarter-by-quarter and country-by-country basis, from sales of ILUVIEN by our licensee. ILUVIEN for DME is expected to be launched in the U.S. in the quarter ending March 31, 2015, while it has been sold in the U.K. and Germany since the quarter ended June 2013, and in Portugal since January 2015. We do not know when or if sales of ILUVIEN will result in future net profits in each country where it is sold, entitling us to our net profits share, or how much we will be entitled to receive.

Research and Development

Research and development increased by \$273,000, or 11%, to \$2.8 million for the three months ended December 31, 2014 from \$2.5 million for the same quarter a year earlier, primarily reflecting increased CRO costs for the clinical development of Medidur for posterior uveitis and personnel-related costs. We expect to continue to incur significant research and development expense for Medidur during the remainder of fiscal year 2015 and in future periods until completion of Medidur clinical development.

[Table of Contents](#)

General and Administrative

General and administrative increased by \$159,000, or 9%, to \$1.9 million for the three months ended December 31, 2014 from \$1.7 million for the same period in the prior year, primarily attributable to increased professional fees and stock-based compensation.

Income Tax Benefit

Income tax benefit was \$38,000 for the three months ended December 31, 2014 compared to \$26,000 for the three months ended December 31, 2013, and consisted of refundable foreign research and development tax credits.

Six Months Ended December 31, 2014 Compared to Six Months Ended December 31, 2013:

	Six Months Ended December 31,		Change	
	2014	2013	Amounts	%
(In thousands except percentages)				
Revenues:				
Collaborative research and development	\$25,245	\$ 473	\$24,772	**
Royalty income	583	716	(133)	(19)%
Total revenues	<u>25,828</u>	<u>1,189</u>	<u>24,639</u>	<u>**</u>
Operating expenses:				
Research and development	5,551	4,998	553	11%
General and administrative	3,604	3,522	82	2%
Gain on sale of property and equipment	—	(72)	72	100%
Total operating expenses	<u>9,155</u>	<u>8,448</u>	<u>707</u>	<u>8%</u>
Income (loss) from operations	16,673	(7,259)	23,932	330%
Interest income	6	2	4	200%
Income (loss) before income taxes	16,679	(7,257)	23,936	330%
Income tax (expense) benefit	(188)	56	(244)	(436)%
Net income (loss)	<u>\$16,491</u>	<u>\$(7,201)</u>	<u>\$23,692</u>	<u>329%</u>

** percentages not meaningful due to the effect of the \$25.0 million non-recurring revenue in the current year-to-date period

Revenues

Collaborative research and development revenues totaled \$25.2 million for the six months ended December 31, 2014 compared to \$473,000 for the six months ended December 31, 2013. This increase was primarily attributable to recognition of the \$25.0 million FDA approval milestone earned for ILUVIEN.

Royalty income decreased by \$133,000, or 19%, to \$583,000 for the six months ended December 31, 2014 compared to \$716,000 for the six months ended December 31, 2013.

Research and Development

Research and development increased by \$553,000, or 11%, to \$5.6 million for the six months ended December 31, 2014 from \$5.0 million for the prior year-to-date period, primarily reflecting increased CRO costs for the clinical development of Medidur for posterior uveitis, higher personnel-related expenses and Tethadur pre-clinical study costs.

[Table of Contents](#)

General and Administrative

General and administrative increased by \$82,000, or 2%, to \$3.6 million for the six months ended December 31, 2014 from \$3.5 million for the same period in the prior year, primarily attributable to increased stock-based compensation, partially offset by lower professional fees and facility costs.

Income Tax (Expense) Benefit

Income tax expense of \$188,000 for the six months ended December 31, 2014 primarily reflected payment of \$260,000 of federal alternative minimum taxes based upon projected taxable income for the tax year ended December 31, 2014. In addition, refundable foreign research and development tax credits totaled \$72,000 and \$56,000 for the six months ended December 31, 2014 and 2013, respectively.

Liquidity and Capital Resources

During the years ended June 30, 2014 and 2013 and the six months ended December 31, 2014, we financed our operations from the receipt of license fees, milestone payments, research and development funding and royalty income from our collaboration partners and from proceeds of sales of equity securities. At December 31, 2014, our principal sources of liquidity were cash, cash equivalents and marketable securities that totaled \$35.7 million.

We have a history of operating losses and, at December 31, 2014, we had a total accumulated deficit of \$260.5 million. We do not currently have any assured sources of future revenue, and we expect negative cash flows from operations on a quarterly basis until such time as we receive sufficient revenues from commercialization of ILUVIEN or one or more of our other product candidates achieve regulatory approval and provide us sufficient revenues. We believe that our capital resources at December 31, 2014 will enable us to fund our current and planned operations into calendar year 2017. This estimate excludes any potential receipts of net profits under our Alimera collaboration agreement. Our ability to fund our planned operations beyond then is expected to depend on cash receipts from ILUVIEN or other products and from any future collaboration or other agreements and/or any financing transactions. There is no assurance that we will receive significant, if any, revenues from sales of ILUVIEN or cash from any other sources.

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

- whether, when and to what extent we receive revenues with respect to commercialization of ILUVIEN;
- the timing and cost of development, approval and marketing of Medidur for posterior uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- whether and when we initiate Phase II clinical trials for the Latanoprost Product and whether and when Pfizer exercises its option;
- 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;
- changes in our operating plan, resulting in increases or decreases in our need for capital; and
- our views on the availability, timing and desirability of raising capital.

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. Our existing ATM facility permits us to sell shares of common stock with an aggregate offering price of up to \$10.7 million at December 31, 2014, but we do not know whether and to what extent we will seek to sell shares pursuant to that program and, if we are able to do

[Table of Contents](#)

so, on what terms. The state of the economy and the financial and credit markets at the time or times we seek any 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.

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

	Six Months Ended December 31,		Change
	2014	2013	
Net income (loss):	\$16,491	\$ (7,201)	\$ 23,692
Changes in operating assets and liabilities	(447)	239	(686)
Other adjustments to reconcile net income (loss) to cash flows from operating activities	1,213	928	285
Net cash provided by (used in) operating activities	<u>\$17,257</u>	<u>\$ (6,034)</u>	<u>\$ 23,291</u>
Net cash (used in) provided by investing activities	<u>\$ (3,065)</u>	<u>\$ 2,751</u>	<u>\$ (5,816)</u>
Net cash provided by financing activities	<u>\$ 235</u>	<u>\$11,601</u>	<u>\$ (11,366)</u>

Net cash provided by operating activities was \$17.3 million for the six months ended December 31, 2014 compared to net cash used in operating activities of \$6.0 million in the prior year period, representing a favorable net change of \$23.2 million. Collaborative research and development and royalty income cash inflows increased by \$23.6 million, primarily the result of the \$25.0 million FDA milestone payment received from Alimera in October 2014, partially offset by lower cash inflows from technology evaluation agreements and Retisert royalties. Operating cash outflows increased by approximately \$270,000 on a comparative basis and consisted primarily of an approximate \$700,000 increase of CRO payments associated with our Medidur clinical development program and \$260,000 of federal alternative minimum taxes, partially offset by an approximate \$560,000 of decreases in incentive compensation awards and professional fees.

Net cash used by investing activities consisted principally of \$3.0 million of purchases of marketable securities, net of maturities, during the six months ended December 31, 2014. This compared to net cash provided by investing activities in the prior year period, which consisted primarily of \$2.85 million of maturities of marketable securities.

Net cash provided by financing activities for the six months ended December 31, 2014 consisted of \$235,000 of proceeds from the exercise of stock options. Net cash provided by financing activities for the six months ended December 31, 2013 consisted of \$9.9 million of net proceeds from a July 2013 underwritten public offering of common shares, \$1.25 million of net proceeds from December 2013 sales of common shares under the ATM facility and \$457,000 of proceeds from the exercise of stock options.

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

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 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 strengthening of the U.S. dollar during the three months ended December 31, 2014 compared to the prior year's quarter resulted in a net decrease in research and development expenses of

[Table of Contents](#)

\$9,000. 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 December 31, 2014 would have decreased or increased by \$21,000, 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 income (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) income, the relative strengthening of the U.S. dollar in relation to the Pound Sterling at December 31, 2014 compared to June 30, 2014 resulted in \$96,000 of other comprehensive loss for the six months ended December 31, 2014 due to the translation of £645,000 of net assets of our U.K. operations, predominantly the BioSilicon (including Tethadur) technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at December 31, 2014 in relation to the Pound Sterling, our stockholders' equity at December 31, 2014 would have decreased or increased, respectively, by \$50,000.

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 December 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 December 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 II, "Item 1A. Risk Factors" of our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2014 filed with the Securities and Exchange Commission (the "SEC") on November 7, 2014.

Item 6. Exhibits

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

pSivida Corp.

Date: February 6, 2015

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;
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 6, 2015

/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;
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 6, 2015

/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, 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: February 6, 2015

/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, 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: February 6, 2015

/s/ Leonard S. Ross

Name: Leonard S. Ross

Title: Vice President, Finance

(Principal Financial Officer)