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

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NUMBER 000-51122

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**pSivida Corp.**

(Exact name of registrant as specified in its charter)

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

**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)

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

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

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

**Large accelerated filer** ☐

**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 34,172,919 shares of the registrant's common stock, \$0.001 par value, outstanding as of May 4, 2016.

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**PSIVIDA CORP. AND SUBSIDIARIES**  
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## PART I. FINANCIAL INFORMATION

### Item 1. Unaudited Financial Statements

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

	March 31, 2016	June 30, 2015
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 24,867	\$ 19,121
Marketable securities	8,407	9,414
Accounts and other receivables	472	622
Prepaid expenses and other current assets	532	681
Total current assets	34,278	29,838
Property and equipment, net	311	338
Intangible assets, net	1,311	1,925
Other assets	115	116
Restricted cash	150	150
<b>Total assets</b>	<u>\$ 36,165</u>	<u>\$ 32,367</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 571	\$ 744
Accrued expenses	3,378	2,571
Deferred revenue	19	33
Total current liabilities	3,968	3,348
Deferred revenue	5,584	5,596
Deferred rent	60	55
<b>Total liabilities</b>	<u>9,612</u>	<u>8,999</u>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$.001 par value, 60,000,000 shares authorized, 34,082,919 and 29,412,365 shares issued and outstanding at March 31, 2016 and June 30, 2015, respectively	34	29
Additional paid-in capital	311,463	293,060
Accumulated deficit	(285,826)	(270,666)
Accumulated other comprehensive income	882	945
Total stockholders' equity	<u>26,553</u>	<u>23,368</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 36,165</u>	<u>\$ 32,367</u>

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)

	<b>Three Months Ended March 31,</b>		<b>Nine Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>Revenues:</b>				
Collaborative research and development	\$ 50	\$ 110	\$ 372	\$25,355
Royalty income	274	218	944	801
Total revenues	324	328	1,316	26,156
<b>Operating expenses:</b>				
Research and development	3,074	3,339	10,277	8,890
General and administrative	2,346	2,041	6,357	5,645
Total operating expenses	5,420	5,380	16,634	14,535
(Loss) income from operations	(5,096)	(5,052)	(15,318)	11,621
Interest and other income	21	10	41	16
(Loss) income before income taxes	(5,075)	(5,042)	(15,277)	11,637
Income tax benefit (expense)	34	44	117	(144)
Net (loss) income	<u>\$ (5,041)</u>	<u>\$ (4,998)</u>	<u>\$ (15,160)</u>	<u>\$11,493</u>
Net (loss) income per common share:				
Basic	<u>\$ (0.15)</u>	<u>\$ (0.17)</u>	<u>\$ (0.49)</u>	<u>\$ 0.39</u>
Diluted	<u>\$ (0.15)</u>	<u>\$ (0.17)</u>	<u>\$ (0.49)</u>	<u>\$ 0.38</u>
<b>Weighted average common shares:</b>				
Basic	<u>33,538</u>	<u>29,412</u>	<u>30,787</u>	<u>29,367</u>
Diluted	<u>33,538</u>	<u>29,412</u>	<u>30,787</u>	<u>30,612</u>
Net (loss) income	<u>\$ (5,041)</u>	<u>\$ (4,998)</u>	<u>\$ (15,160)</u>	<u>\$11,493</u>
<b>Other comprehensive loss:</b>				
Foreign currency translation adjustments	(21)	(45)	(68)	(141)
Net unrealized gain (loss) on marketable securities	9	1	5	(4)
Other comprehensive loss	(12)	(44)	(63)	(145)
Comprehensive (loss) income	<u>\$ (5,053)</u>	<u>\$ (5,042)</u>	<u>\$ (15,223)</u>	<u>\$11,348</u>

See notes to condensed consolidated financial statements

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

	<b>Common Stock</b>		<b>Additional Paid-In Capital</b>	<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Income</b>	<b>Total Stockholders' Equity</b>
	<b>Number of Shares</b>	<b>Par Value Amount</b>				
Balance at July 1, 2014	29,298,558	\$ 29	\$290,864	\$ (277,013)	\$ 1,044	\$ 14,924
Net income	—	—	—	11,493	—	11,493
Other comprehensive loss	—	—	—	—	(145)	(145)
Exercise of stock options	113,807	—	235	—	—	235
Stock-based compensation	—	—	1,340	—	—	1,340
Balance at March 31, 2015	<u>29,412,365</u>	<u>\$ 29</u>	<u>\$292,439</u>	<u>\$ (265,520)</u>	<u>\$ 899</u>	<u>\$ 27,847</u>
Balance at July 1, 2015	29,412,365	\$ 29	\$293,060	\$ (270,666)	\$ 945	\$ 23,368
Net loss	—	—	—	(15,160)	—	(15,160)
Other comprehensive loss	—	—	—	—	(63)	(63)
Issuance of stock, net of issue costs	4,440,000	5	16,496	—	—	16,501
Exercise of stock options	230,554	—	358	—	—	358
Stock-based compensation	—	—	1,549	—	—	1,549
Balance at March 31, 2016	<u>34,082,919</u>	<u>\$ 34</u>	<u>\$311,463</u>	<u>\$ (285,826)</u>	<u>\$ 882</u>	<u>\$ 26,553</u>

See notes to condensed consolidated financial statements

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

	<b>Nine Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net (loss) income	\$(15,160)	\$11,493
Adjustments to reconcile net (loss) income to cash flows from operating activities:		
Amortization of intangible assets	569	579
Depreciation of property and equipment	88	79
Stock-based compensation expense	1,549	1,340
Amortization of bond premium on marketable securities	86	66
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	284	(388)
Accounts payable and accrued expenses	635	221
Deferred revenue	(25)	(103)
Deferred rent	5	16
Net cash (used in) provided by operating activities	<u>(11,969)</u>	<u>13,303</u>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(10,242)	(8,677)
Maturities of marketable securities	11,168	2,900
Purchases of property and equipment	(67)	(71)
Net cash provided by (used in) investing activities	<u>859</u>	<u>(5,848)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of stock, net of issuance costs	16,510	—
Exercise of stock options	358	235
Net cash provided by financing activities	<u>16,868</u>	<u>235</u>
Effect of foreign exchange rate changes on cash and cash equivalents	(12)	(17)
<b>Net increase in cash and cash equivalents</b>	5,746	7,673
<b>Cash and cash equivalents at beginning of period</b>	<u>19,121</u>	<u>15,334</u>
<b>Cash and cash equivalents at end of period</b>	<u><u>\$ 24,867</u></u>	<u><u>\$23,007</u></u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for income taxes	\$ 4	\$ 263

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, 2016 and for the three and nine months ended March 31, 2016 and 2015 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, 2015. 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, 2015, 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 nine months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the entire fiscal year or any future period.

The Company develops sustained-release drug delivery products primarily for the treatment of chronic eye diseases. Its products deliver drugs at a controlled and steady rate for months or years. The Company has developed three of only four sustained-release products approved by the U.S. Food and Drug Administration (“FDA”) for treatment of back-of-the-eye diseases. Medidur™ for posterior uveitis, the Company’s lead product candidate, is in pivotal Phase III clinical trials, and ILUVIEN® for diabetic macular edema (“DME”), its lead licensed product, is sold in the U.S. and three European Union (“EU”) countries. The Company’s pre-clinical development program is focused primarily on developing products utilizing the Company’s two core technology platforms, Durasert™ and Tethadur™. The Company’s strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements as appropriate.

Medidur, the Company’s most advanced development product, is a sustained-release micro-insert designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (“posterior uveitis”). Medidur, which is designed to provide sustained treatment for three years from a single injection, is being studied in two Phase III trials. In December 2015, the Company announced positive top-line results from the first Phase III trial, which met its primary efficacy endpoint with high statistical significance and achieved positive safety results. Enrollment in the second Phase III trial is ongoing. Assuming favorable results from the second trial, the Company plans to file a new drug application (“NDA”) with the FDA around mid-2017 based on the results from both trials, data from a short-duration utilization study of its redesigned proprietary inserter and data referenced from the Phase III trials of ILUVIEN. Due to the high level of statistical significance achieved in the first trial, the Company plans to file for EU marketing approval based on the results of that single Phase III trial rather than both trials. The Company is developing Medidur independently.

ILUVIEN, the Company’s most recently approved product, is a sustained-release micro-insert that provides treatment of DME. Like Medidur, it is injected into the eye in an office visit and provides three years of treatment from a single injection. 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 quarter-by-quarter, country-by-country basis. ILUVIEN was launched in the U.S. in late February 2015, where it is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure. ILUVIEN has been commercially available in the United Kingdom and Germany since June 2013 and in Portugal since January 2015. ILUVIEN has marketing approvals in 17 EU countries for the treatment of chronic DME considered insufficiently responsive to available therapies.

The Company’s FDA-approved Retisert® is a surgical implant that provides sustained release treatment of posterior uveitis for approximately two and a half years. It is licensed to Bausch & Lomb, and the Company receives royalties from its sales.



The Company's pre-clinical development program is focused on developing products using its Durasert™ and Tethadur™ technology platforms to deliver drugs and biologics to treat wet and dry age-related macular degeneration ("AMD"), glaucoma, osteoarthritis and other diseases.

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 \$33.3 million at March 31, 2016, together with expected cash inflows under existing collaboration agreements, will enable the Company to maintain its current and planned operations (including its two Medidur Phase III clinical trials) into the fourth quarter of calendar year 2017. This estimate excludes any potential future receipts from the commercialization of ILUVIEN. 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 any cash receipts under the ILUVIEN collaboration agreement and the proceeds from any future collaboration or other agreements and/or financing transactions.

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. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 will become effective on July 1, 2018, with early adoption permitted on July 1, 2017. 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.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern*. ASU 2014-15 provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted. The Company is evaluating the potential impact of adopting this standard on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its pending adoption of the new standard on its financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 intends to simplify various aspects of how share-based payments are accounted for and presented in the financial statements. The main provisions include: all tax effects related to stock awards will now be recorded through the statement of operations instead of through equity, all tax-related cash flows resulting from stock awards will be reported as operating activities on the cash flow statement, and entities can make an accounting policy election to either estimate forfeitures or account for forfeitures as they occur. The amendments in ASU 2016-09 are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and may be applied prospectively with earlier adoption permitted. The Company is currently evaluating the impact of this guidance on its consolidated 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 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. If 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 is also entitled to reimbursement of certain patent maintenance costs with respect to the patents licensed to Alimera.

Because the Company has no remaining performance obligations under the Alimera Agreement, all amounts received from Alimera 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 under the Alimera Agreement totaled \$35,000 and \$70,000 for the three months ended March 31, 2016 and 2015, respectively, and \$226,000 and \$25.1 million for the nine months ended March 31, 2016 and 2015, respectively. These revenues consisted of \$157,000 of non-royalty sublicense consideration earned during the three months ended September 30, 2015 and a \$25.0 million milestone earned as a result of the FDA approval of ILUVIEN during the three months ended September 30, 2014, with the remainder having 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 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 to date have not been undertaken, 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. As of March 31, 2016, the Company continues to evaluate whether to undertake Phase II clinical trials and, consequently, the Company cannot currently estimate the remaining performance period and has therefore not recognized any additional revenue. As a result, the current portion of deferred revenue was \$0 at each of March 31, 2016 and June 30, 2015. Total deferred revenue was approximately \$5.6 million at each of March 31, 2016 and June 30, 2015. The Company recorded no collaborative research and development revenue during each of the three and nine-month periods ended March 31, 2016 and 2015. Costs associated with developing the Latanoprost Product are reflected in operating expenses in the period in which they are incurred.

Pfizer owned approximately 5.5% of the Company’s outstanding common stock at March 31, 2016.

## **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 \$274,000 and \$218,000 for the three months ended March 31, 2016 and 2015, respectively, and \$944,000 and \$801,000 for the nine months ended March 31, 2016 and 2015, respectively. In addition, patent fee reimbursements of \$6,000 for each of the three month periods ended March 31, 2016 and 2015, and \$20,000 and \$19,000 for the nine months ended March 31, 2016 and 2015, respectively, have been included in collaborative research and development revenue. Accounts receivable from Bausch & Lomb totaled \$280,000 at March 31, 2016 and \$371,000 at June 30, 2015.

## **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 most recent of which was received in December 2015. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any licensed patent maintenance costs, sales-based royalties and sub-licensee 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. There was no revenue related to the Enigma agreement in either of the three-month periods ended March 31, 2016 and 2015 and \$100,000 of revenue for both of the nine-month periods ended March 31, 2016 and 2015. As of March 31, 2016, 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. Revenues under evaluation agreements totaled \$8,000 and \$35,000 for the three months ended March 31, 2016 and 2015, respectively, and \$25,000 and \$104,000 for the nine months ended March 31, 2016 and 2015, respectively.

## **3. Intangible Assets**

The reconciliation of intangible assets for the nine months ended March 31, 2016 and for the year ended June 30, 2015 was as follows (in thousands):

	Nine Months Ended March 31, 2016	Year Ended June 30, 2015
<b>Patented technologies</b>		
Gross carrying amount at beginning of period	\$ 39,710	\$ 41,689
Foreign currency translation adjustments	(2,038)	(1,979)
Gross carrying amount at end of period	37,672	39,710
Accumulated amortization at beginning of period	(37,785)	(38,924)
Amortization expense	(569)	(770)
Foreign currency translation adjustments	1,993	1,909
Accumulated amortization at end of period	(36,361)	(37,785)
Net book value at end of period	<u>\$ 1,311</u>	<u>\$ 1,925</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 \$187,000 and \$190,000 for the three months ended March 31, 2016 and 2015, respectively, and \$569,000 and \$579,000 for the nine months ended March 31, 2016 and 2015, respectively. The carrying value of intangible assets at March 31, 2016 of \$1.3 million (\$927,000 attributable to the Durasert technology and \$384,000 attributable to the BioSilicon technology (including Tethadur)) is expected to be amortized on a straight-line basis over the remaining estimated useful life of 1.75 years, or approximately \$750,000 per year.

#### 4. Marketable Securities

The amortized cost, unrealized loss and fair value of the Company's available-for-sale marketable securities at March 31, 2016 and June 30, 2015 were as follows (in thousands):

	March 31, 2016		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	\$ 4,416	\$ —	\$4,416
Commercial paper	3,491	—	3,491
Government agency	500	—	500
Total marketable securities	<u>\$ 8,407</u>	<u>\$ —</u>	<u>\$8,407</u>

  

	June 30, 2015		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	<u>\$ 9,419</u>	<u>\$ (5)</u>	<u>\$9,414</u>

During the nine months ended March 31, 2016, \$10.2 million of marketable securities were purchased and \$11.2 million of such securities matured. At March 31, 2016, the marketable securities had maturities ranging from 6 days to 7.5 months, with a weighted average maturity of 4.0 months.

#### 5. Fair Value Measurements

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

- Level 1 – Inputs are quoted prices (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, 2016 and June 30, 2015, 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. These deposits may be redeemed upon demand and, therefore, generally have 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, 2016 and June 30, 2015 by valuation hierarchy (in thousands):

March 31, 2016				
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 21,607	\$ 20,106	\$ 1,501	\$ —
Marketable securities				
Corporate bonds	4,416	3,913	503	—
Commercial paper	3,491	—	3,491	—
Government agency	500	—	500	—
	<u>\$ 30,014</u>	<u>\$ 24,019</u>	<u>\$ 5,995</u>	<u>\$ —</u>
June 30, 2015				
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 15,835	\$ 15,835	\$ —	\$ —
Marketable securities				
Corporate bonds	9,414	7,413	2,001	—
	<u>\$ 25,249</u>	<u>\$ 23,248</u>	<u>\$ 2,001</u>	<u>\$ —</u>

## 6. Accrued Expenses

Accrued expenses consisted of the following at March 31, 2016 and June 30, 2015 (in thousands):

	March 31, 2016	June 30, 2015
Clinical trial costs	\$ 2,194	\$ 1,424
Personnel costs	684	735
Professional fees	452	384
Other	48	28
	<u>\$ 3,378</u>	<u>\$ 2,571</u>

## 7. Stockholders' Equity

In January 2016, the Company sold 4,440,000 shares of its common stock in an underwritten public offering at a price of \$4.00 per share for gross proceeds of \$17.8 million. Underwriter discounts and commissions and other share issue costs totaled approximately \$1.3 million.

In December 2013, the Company entered into an at-the-market ("ATM") program pursuant to which the Company may offer and sell shares of its common stock from time to time for an aggregate offering price of up to \$19.2 million, of which approximately \$17.6 million remains unsold. The Company pays the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. The Company's ability to sell shares under the ATM program is subject to an Australian Securities Exchange ("ASX") rule limiting the number of shares the Company may issue in any 12-month period without shareholder approval, as well as other applicable rules and regulations of ASX and the NASDAQ Global Market. During the three and nine-month periods ended March 31, 2016 and 2015, the Company did not sell any shares under this program.

## Warrants to Purchase Common Shares

The following table provides a reconciliation of warrants to purchase common stock for the nine months ended March 31, 2016 and 2015:

	Nine Months Ended March 31,			
	2016		2015	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	1,176,105	\$ 3.67	1,176,105	\$ 3.67
Expired	(552,500)	5.00	—	—
Balance and exercisable at end of period	<u>623,605</u>	<u>\$ 2.50</u>	<u>1,176,105</u>	<u>\$ 3.67</u>

At March 31, 2016, the remaining term of these warrants was 1.35 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 March 31, 2016, a total of 7,091,255 shares of common stock were authorized for issuance under the 2008 Plan, of which 1,019,791 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 nine months ended March 31, 2016:

	<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, 2015	4,447,975	\$ 3.36		
Granted	854,000	4.08		
Exercised	(230,554)	1.56		
Outstanding at March 31, 2016	<u>5,071,421</u>	<u>\$ 3.56</u>	<u>6.03</u>	<u>\$ 977</u>
Outstanding at March 31, 2016 - vested or unvested and expected to vest	<u>4,979,785</u>	<u>\$ 3.55</u>	<u>5.99</u>	<u>\$ 974</u>
Exercisable at March 31, 2016	<u>3,310,234</u>	<u>\$ 3.32</u>	<u>4.71</u>	<u>\$ 930</u>

During the nine months ended March 31, 2016, the Company granted 744,000 options to employees with ratable annual vesting over 4 years and 110,000 options to non-executive directors with 1-year cliff vesting. All option grants have a 10-year term. The weighted-average grant date fair value of these options was \$2.74 per share. A total of 646,605 options vested during the nine months ended March 31, 2016. 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, 2016 based on the following key assumptions:

Option life (in years)	5.50 - 6.25
Stock volatility	76% - 80%
Risk-free interest rate	1.47% - 1.97%
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 nine months ended March 31, 2016 and 2015 as follows (in thousands):

	<u>Three Months Ended March 31,</u>		<u>Nine Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Compensation expense included in:				
Research and development	\$ 180	\$ 182	\$ 521	\$ 492
General and administrative	<u>481</u>	<u>432</u>	<u>1,028</u>	<u>848</u>
	<u>\$ 661</u>	<u>\$ 614</u>	<u>\$1,549</u>	<u>\$1,340</u>

At March 31, 2016, there was approximately \$2.3 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 not more likely than not that all or a portion of the deferred tax assets will 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 \$34,000 and \$117,000 for the three and nine months ended March 31, 2016, respectively, an income tax benefit of \$44,000 for the three months ended March 31, 2015 and an income tax expense of \$144,000 for the nine months ended March 31, 2015. The Company recorded \$4,000 and \$263,000 of federal alternative minimum tax expense for the nine months ended March 31, 2016 and 2015, respectively, as a result of taxable income for the tax year ended December 31, 2014, which was primarily attributable to revenue recognition 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 nine months ended March 31, 2016 and 2015, the Company had no significant unrecognized tax benefits. At March 31, 2016 and June 30, 2015, the Company had no accrued penalties or interest related to uncertain tax positions.

## 9. Commitments and Contingencies

In March 2014, the Company leased U.S. office and laboratory space in Watertown, Massachusetts and 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. 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 is 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 March 31,</u>		<u>Nine Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Number of common shares - basic	33,537,589	29,412,365	30,786,711	29,366,919
Effect of dilutive securities:				
Stock options	—	—	—	989,990
Warrants	—	—	—	255,301
Number of common shares - diluted	<u>33,537,589</u>	<u>29,412,365</u>	<u>30,786,711</u>	<u>30,612,210</u>

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 March 31,</u>		<u>Nine Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Options outstanding	5,071,421	4,490,949	5,071,421	1,881,524
Warrants outstanding	623,605	1,176,105	623,605	552,500
	<u>5,695,026</u>	<u>5,667,054</u>	<u>5,695,026</u>	<u>2,434,024</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: our ability to achieve profitable operations and access to capital; fluctuations in operating results; further impairment of our intangible assets; declines in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; safety and efficacy results of the second Medidur Phase III trial, number of trials and data required to file for, timing of filing and acceptance of, the Medidur NDA and EU marketing approval applications, if at all; ability to use data in a U.S. NDA from trials outside the U.S.; any exercise by Pfizer of its option with respect to the Latanoprost product; our ability to develop Tethadur to successfully deliver large biologic molecules and develop products using it; our ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; our ability to market and sell products; the success of current and future license agreements; termination or breach of current 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 makes it clear that any projected results expressed or implied in such statements will not be realized.

### **Our Business**

We develop sustained-release drug delivery products primarily for the treatment of chronic eye diseases. Our products deliver drugs at a controlled and steady rate for months or years. We have developed three of only four sustained-release products approved by the U.S. Food and Drug Administration ("FDA") for treatment of back-of-the-eye diseases. Medidur™ for posterior uveitis, our lead product candidate, is in pivotal Phase III clinical trials, and ILUVIEN® for diabetic macular edema ("DME"), our lead licensed product, is sold in the U.S. and three European Union ("EU") countries. Our pre-clinical development program is focused primarily on developing products utilizing our two core technology platforms, Durasert™ and Tethadur™. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaborations and license agreements as appropriate.

Medidur, our most advanced development product, is a sustained-release micro-insert designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye ("posterior uveitis"). Injected into the eye in an office visit using a 27 gauge inserter, Medidur is designed to provide sustained treatment for three years from a single injection. The tiny 3.5 mm micro-insert delivers 180 micrograms of the corticosteroid fluocinolone acetonide ("FA") over three years.

Medidur is in two Phase III clinical trials. In December 2015, we announced positive top-line results from the first trial. The 129 patient, multi-center, randomized and double-blinded trial was highly statistically significant in meeting its primary efficacy endpoint of prevention of recurrence of disease at six months (p less than 0.00000001; intent to treat analysis). Safety results were also positive. Only 10.9% more Medidur-treated eyes than control eyes experienced an increase in intraocular pressure (“IOP”) above 21 mmHg through six months. Assuming favorable results from the second Phase III trial, we plan to file a new drug application (“NDA”) with the FDA around mid-2017 based the results from both trials and data from a short-duration utilization study of our redesigned proprietary inserter, together with data referenced from the Phase III trials of ILUVIEN. Due to the high level of statistical significance achieved in the first trial, we plan to file for EU marketing approval under the Centralized Procedure based on the results of that single Phase III trial, rather than both trials. Medidur has been designated an orphan medicinal product in Europe. We are developing Medidur independently.

ILUVIEN®, our most recently approved product, is a sustained-release micro-insert that provides treatment of DME. Like Medidur, it is injected into the eye in an office visit and provides three years of treatment from a single administration. ILUVIEN is a tiny 3.5 mm micro-insert of the same design as Medidur, inserted in an office visit using a 25 gauge inserter, delivering 190 micrograms of FA over three years. 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 quarter-by-quarter, country-by-country basis. ILUVIEN was launched in the U.S. in late February 2015, where it is indicated for the treatment of DME in patients previously treated with a course of corticosteroids without a clinically significant rise in IOP. ILUVIEN has been commercially available in the United Kingdom and Germany since June 2013 and in Portugal since January 2015. ILUVIEN has marketing approvals in 17 EU countries for the treatment of chronic DME considered insufficiently responsive to available therapies.

Our FDA-approved Retisert® is a surgical implant which treats posterior uveitis by providing sustained release of .59 milligrams (590 micrograms) of FA over approximately two and a half years. It is licensed to Bausch & Lomb, and we receive royalties from its sales.

Our pre-clinical development program is focused on developing products using our Durasert™ and Tethadur™ technology platforms to deliver drugs and biologics to treat wet and dry age-related macular degeneration (“AMD”), glaucoma, osteoarthritis and other diseases.

Durasert™, Medidur™, BioSilicon™ and Tethadur™ are our trademarks, Retisert® is Bausch & Lomb’s registered trademark, and ILUVIEN® is Alimera’s registered 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 publicly 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, 2015 (“fiscal year 2015”), we set forth our critical accounting policies and estimates, which included revenue recognition and recognition of expense in outsourced clinical trial agreements. 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 2015.

## Results of Operations

### Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015:

	Three Months Ended March 31,		Change	
	2016	2015	Amounts	%
(In thousands except percentages)				
Revenues:				
Collaborative research and development	\$ 50	\$ 110	\$ (60)	(55)%
Royalty income	274	218	56	26%
Total revenues	324	328	(4)	(1)%
Operating expenses:				
Research and development	3,074	3,339	(265)	(8)%
General and administrative	2,346	2,041	305	15%
Total operating expenses	5,420	5,380	40	1%
Loss from operations	(5,096)	(5,052)	(44)	(1)%
Interest and other income	21	10	11	110%
Loss before income taxes	(5,075)	(5,042)	(33)	(1)%
Income tax benefit	34	44	(10)	(23)%
Net loss	<u><u>\$ (5,041)</u></u>	<u><u>\$ (4,998)</u></u>	<u><u>\$ (43)</u></u>	<u><u>(1)%</u></u>

#### Revenues

Collaborative research and development revenues totaled \$50,000 for the three months ended March 31, 2016 compared to \$110,000 for the three months ended March 31, 2015.

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 and are also entitled to 20% of royalties and 33% of non-royalty consideration received by our licensee from sublicensees. We received \$0 and \$31,000 of net profits from Alimera's sales of ILUVIEN in the three months ended March 31, 2016 and 2015, respectively. We do not know if, or when, we will receive future payments from the commercialization of ILUVIEN or the amount of any such payments.

Royalty income increased by \$56,000, or 26%, to \$274,000 for the three months ended March 31, 2016 compared to \$218,000 for the three months ended March 31, 2015.

#### Research and Development

Research and development expense decreased by \$265,000, or 8%, to \$3.1 million for the three months ended March 31, 2016 from \$3.3 million for the same quarter a year earlier, primarily attributable to a \$486,000 decrease in contract research organization ("CRO") costs, partially offset by an increase of approximately \$90,000 in personnel costs, for the Medidur clinical development program. We expect to continue to incur significant research and development expense for Medidur in the fiscal 2016 fourth quarter and in future periods until completion of Medidur clinical development.

#### General and Administrative

General and administrative expense increased by \$305,000, or 15%, to \$2.3 million for the three months ended March 31, 2016 from \$2.0 million for the same period in the prior year, primarily attributable to higher professional fees and personnel costs, including stock-based compensation.

### ***Income Tax Benefit***

Income tax benefit was \$34,000 for the three months ended March 31, 2016 compared to \$44,000 for the three months ended March 31, 2015, and consisted predominantly of refundable foreign research and development tax credits.

### **Nine Months Ended March 31, 2016 Compared to Nine Months Ended March 31, 2015:**

	Nine Months Ended March 31,		Change	
	2016	2015	Amounts	%
(In thousands except percentages)				
Revenues:				
Collaborative research and development	\$ 372	\$25,355	\$(24,983)	**
Royalty income	944	801	143	18%
Total revenues	1,316	26,156	(24,840)	**
Operating expenses:				
Research and development	10,277	8,890	1,387	16%
General and administrative	6,357	5,645	712	13%
Total operating expenses	16,634	14,535	2,099	14%
(Loss) income from operations	(15,318)	11,621	(26,939)	(232)%
Interest and other income	41	16	25	156%
(Loss) income before income taxes	(15,277)	11,637	(26,914)	(231)%
Income tax benefit (expense)	117	(144)	261	181%
Net (loss) income	<u>\$(15,160)</u>	<u>\$11,493</u>	<u>\$(26,653)</u>	<u>(232)%</u>

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

### ***Revenues***

Collaborative research and development revenues totaled \$372,000 for the nine months ended March 31, 2016 compared to \$25.4 million for the nine months ended March 31, 2015. The fiscal 2015 nine-month period reflected the recognition of the \$25.0 million FDA-approval milestone for ILUVIEN.

Royalty income increased by \$143,000, or 18%, to \$944,000 for the nine months ended March 31, 2016 compared to \$801,000 for the nine months ended March 31, 2015.

### ***Research and Development***

Research and development expense increased by approximately \$1.4 million, or 16%, to \$10.3 million for the nine months ended March 31, 2016 from \$8.9 million for the prior year-to-date period. This consisted primarily of an increase of approximately \$1.3 million for the Medidur clinical development program, including approximately \$780,000 of CRO costs, \$215,000 of other third-party research costs, \$175,000 of personnel costs and \$100,000 of professional fees.

### ***General and Administrative***

General and administrative expense increased by \$712,000, or 13%, to \$6.4 million for the nine months ended March 31, 2016 from \$5.6 million for the same period in the prior year, primarily attributable to increases of approximately \$305,000 for professional fees, \$180,000 for stock-based compensation, \$145,000 for personnel costs and \$50,000 for director fees.

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

Income tax benefit was \$117,000 for the nine months ended March 31, 2016 compared to income tax expense of \$144,000 for the nine months ended March 31, 2015. Federal alternative minimum tax expense totaled \$4,000 and \$263,000 for the nine months ended March 31, 2016 and 2015, respectively. In addition, refundable foreign research and development tax credits totaled \$121,000 and \$119,000 for the nine months ended March 31, 2016 and 2015, respectively.

### **Liquidity and Capital Resources**

During fiscal 2015 and the first three quarters of the current fiscal year, we financed our operations primarily from the \$25.0 million ILUVIEN FDA-approval milestone received in the quarter ended December 31, 2014 and \$16.5 million of net proceeds from an underwritten public offering of common shares in January 2016. At March 31, 2016, our principal sources of liquidity were cash, cash equivalents and marketable securities that totaled \$33.3 million.

With the exception of net income in fiscal 2015 resulting from the \$25.0 million milestone, we have generally incurred operating losses since inception, and at March 31, 2016, we had a total accumulated deficit of \$285.8 million. We have financed our operations primarily 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 our equity securities. We do not currently have any assured sources of future revenue, and we expect negative cash flows from operations in subsequent quarters unless and until such time as we receive sufficient revenues from the commercialization of ILUVIEN and/or of Medidur or another product candidate, assuming regulatory approval. We believe that our capital resources at March 31, 2016, together with expected cash inflows under existing collaboration agreements, will enable us to fund our operations as currently planned into the fourth quarter of calendar year 2017. This estimate excludes any potential receipts under our ILUVIEN collaboration agreement. Our ability to fund our planned operations beyond then, including completion of clinical development and commercialization of Medidur, is expected to depend on the amount and timing of any cash receipts under the ILUVIEN collaboration agreement and/or proceeds from any future collaboration, licensing or other agreements and/or any proceeds from financing transactions. There is no assurance that we will receive significant, if any, revenues from the commercialization of ILUVIEN or cash from any other sources.

Whether we will require, or desire, to raise additional capital through agreements or financing transactions 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, commercialization and marketing of Medidur for posterior uveitis, including the manner in which it would be commercialized;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct 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 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 and maintaining patents, and defending and enforcing 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. We do not know if collaboration, licensing or other agreements will be available on favorable terms, or at all. Although we may be able to sell common shares under our existing ATM facility, we do not know whether and to what extent we will seek to do so and, if we 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. We may also need to obtain shareholder approval for future sales of common shares under certain circumstances due to the rules and regulations of the Australian Securities Exchange and the NASDAQ Global Market, which may delay or prevent us from raising additional capital. 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 delay, reduce the scope of, or eliminate research or development programs, potential independent commercialization of new products, if any, 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
	2016	2015	
Net (loss) income:	\$(15,160)	\$11,493	\$(26,653)
Changes in operating assets and liabilities	899	(254)	1,153
Other adjustments to reconcile net (loss) income to cash flows from operating activities	2,292	2,064	228
Net cash (used in) provided by operating activities	\$(11,969)	\$13,303	\$(25,272)
Net cash provided by (used in) investing activities	\$ 859	\$(5,848)	\$ 6,707
Net cash provided by financing activities	\$ 16,868	\$ 235	\$ 16,633

Net cash used in operating activities was \$12.0 million for the nine months ended March 31, 2016 compared to net cash provided by operating activities of \$13.3 million for the nine months ended March 31, 2015. Collaborative research and development and royalty income cash inflows decreased by \$24.7 million, primarily as a result of the \$25.0 million ILUVIEN FDA-approval milestone received in the quarter ended December 31, 2014, partially offset by \$157,000 of ILUVIEN sublicense consideration received in the quarter ended September 30, 2015 and a \$155,000 increase in Retisert royalty income payments received in the nine months ended March 31, 2016. Operating cash outflows, net, increased by \$524,000 on a comparative basis and consisted primarily of a \$448,000 increase in professional fees, a \$245,000 increase in pre-clinical and other third party research costs and a \$77,000 increase in Medidur clinical development costs, partially offset by a \$260,000 decrease in federal alternative minimum tax paid in connection with the tax year ended December 31, 2014.

Net cash provided by investing activities for the nine months ended March 31, 2016 consisted principally of \$926,000 of maturities of marketable securities, net of purchases. Net cash used in investing activities for the nine months ended March 31, 2015 consisted principally of \$5.8 million of purchases of marketable securities, net of maturities.

Net cash provided by financing activities for the nine months ended March 31, 2016 consisted of \$16.5 million of net proceeds from a January 2016 underwritten public offering of 4,440,000 common shares and \$358,000 of proceeds from the exercise of stock options. Net cash provided by financing activities for the nine months ended March 31, 2015 consisted of \$235,000 of proceeds from the exercise of stock options.

We had no borrowings or line of credit facilities as of March 31, 2016.

## **Off-Balance Sheet Arrangements**

We had no off-balance sheet arrangements as of March 31, 2016 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 March 31, 2016 compared to the prior year's quarter resulted in a net decrease in research and development expenses of \$27,000. 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, 2016 would have decreased or increased by \$23,000, 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) income 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 March 31, 2016 compared to June 30, 2015 resulted in \$68,000 of other comprehensive loss for the nine months ended March 31, 2016 due to the translation of £414,000 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 March 31, 2016 in relation to the Pound Sterling, our stockholders' equity at March 31, 2016 would have decreased or increased, respectively, by \$30,000.

## **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, 2016. 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. 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, 2016, 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, 2015 filed with the Securities and Exchange Commission (the “SEC”) on September 10, 2015.

### **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, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Comprehensive (Loss) Income; (iii) Condensed Consolidated Statements 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: May 6, 2016

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 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 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 6, 2016

/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 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 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 6, 2016

/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, 2016, 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 6, 2016

/s/ Paul Ashton

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Name: Paul Ashton

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

**Certification of Principal Financial Officer pursuant to 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, 2016, 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 6, 2016

/s/ Leonard S. Ross

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Name: Leonard S. Ross

Title: Vice President, Finance  
(Principal Financial Officer)