

PSIVIDA CORP.

FORM 10-Q (Quarterly Report)

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

FORM 10-Q

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

For the quarterly period ended March 31, 2017

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 39,268,692 shares of the registrant's common stock, \$0.001 par value, outstanding as of May 4, 2017.

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, 2017	June 30, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,871	\$ 15,313
Marketable securities	2,499	13,679
Accounts and other receivables	300	488
Prepaid expenses and other current assets	800	483
Total current assets	16,470	29,963
Property and equipment, net	241	290
Intangible assets, net	540	1,102
Other assets	104	114
Restricted cash	150	150
Total assets	\$ 17,505	\$ 31,619
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 741	\$ 1,363
Accrued expenses	3,943	3,583
Deferred revenue	256	147
Total current liabilities	4,940	5,093
Deferred revenue	—	5,585
Deferred rent	55	60
Total liabilities	4,995	10,738
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, 35,668,685 and 34,172,919 shares issued and outstanding at March 31, 2017 and June 30, 2016, respectively	35	34
Additional paid-in capital	316,233	312,208
Accumulated deficit	(304,582)	(292,213)
Accumulated other comprehensive income	824	852
Total stockholders' equity	12,510	20,881
Total liabilities and stockholders' equity	\$ 17,505	\$ 31,619

See notes to condensed consolidated financial statements

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

	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2017	2016	2017	2016
Revenues:				
Collaborative research and development	\$ 372	\$ 50	\$ 6,108	\$ 372
Royalty income	218	274	730	944
Total revenues	<u>590</u>	<u>324</u>	<u>6,838</u>	<u>1,316</u>
Operating expenses:				
Research and development	3,324	3,074	10,667	10,277
General and administrative	2,426	2,346	8,611	6,357
Total operating expenses	<u>5,750</u>	<u>5,420</u>	<u>19,278</u>	<u>16,634</u>
Loss from operations	(5,160)	(5,096)	(12,440)	(15,318)
Interest and other income	20	21	71	41
Loss before income taxes	(5,140)	(5,075)	(12,369)	(15,277)
Income tax benefit	—	34	—	117
Net loss	<u>\$ (5,140)</u>	<u>\$ (5,041)</u>	<u>\$ (12,369)</u>	<u>\$ (15,160)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.15)</u>	<u>\$ (0.36)</u>	<u>\$ (0.49)</u>
Weighted average common shares:				
Basic and diluted	<u>34,366</u>	<u>33,538</u>	<u>34,238</u>	<u>30,787</u>
Net loss	<u>\$ (5,140)</u>	<u>\$ (5,041)</u>	<u>\$ (12,369)</u>	<u>\$ (15,160)</u>
Other comprehensive income (loss):				
Foreign currency translation adjustments	—	(21)	(30)	(68)
Net unrealized gain on marketable securities	1	9	2	5
Other comprehensive income (loss)	<u>1</u>	<u>(12)</u>	<u>(28)</u>	<u>(63)</u>
Comprehensive loss	<u>\$ (5,139)</u>	<u>\$ (5,053)</u>	<u>\$ (12,397)</u>	<u>\$ (15,223)</u>

See notes to condensed consolidated financial statements

PSIVIDA CORP. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS 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, 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>
Balance at July 1, 2016	34,172,919	\$ 34	\$ 312,208	\$ (292,213)	\$ 852	\$ 20,881
Net loss	—	—	—	(12,369)	—	(12,369)
Other comprehensive loss	—	—	—	—	(28)	(28)
Issuance of stock, net of issue costs	1,411,686	1	2,152	—	—	2,153
Exercise of stock options	84,080	—	99	—	—	99
Stock-based compensation	—	—	1,774	—	—	1,774
Balance at March 31, 2017	<u>35,668,685</u>	<u>\$ 35</u>	<u>\$ 316,233</u>	<u>\$ (304,582)</u>	<u>\$ 824</u>	<u>\$ 12,510</u>

See notes to condensed consolidated financial statements

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

	Nine Months Ended	
	March 31,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$(12,369)	\$(15,160)
Adjustments to reconcile net loss to cash flows from operating activities:		
Amortization of intangible assets	542	569
Depreciation of property and equipment	59	88
Stock-based compensation expense	1,774	1,549
Amortization of bond (discount) premium on marketable securities	(9)	86
Amortization of noncurrent portion of deferred revenue	(5,584)	—
Changes in current assets and liabilities:		
Accounts receivable and other current assets	(131)	284
Accounts payable and accrued expenses	(424)	635
Deferred revenue	109	(25)
Deferred rent	(5)	5
Net cash used in operating activities	<u>(16,038)</u>	<u>(11,969)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(5,052)	(10,242)
Maturities of marketable securities	16,243	11,168
Purchases of property and equipment	(21)	(67)
Proceeds from sale of property and equipment	33	—
Net cash provided by investing activities	<u>11,203</u>	<u>859</u>
Cash flows from financing activities:		
Issuance of stock, net of issue costs	2,305	16,510
Exercise of stock options	99	358
Net cash provided by financing activities	<u>2,404</u>	<u>16,868</u>
Effect of foreign exchange rate changes on cash and cash equivalents	(11)	(12)
Net (decrease) increase in cash and cash equivalents	<u>(2,442)</u>	<u>5,746</u>
Cash and cash equivalents at beginning of period	<u>15,313</u>	<u>19,121</u>
Cash and cash equivalents at end of period	<u>\$ 12,871</u>	<u>\$ 24,867</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment	\$ 22	\$ —
Stock issuance costs	152	—

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, 2017 and for the three and nine months ended March 31, 2017 and 2016 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, 2016 (“fiscal 2016”). 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, 2016, and include all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair presentation of the Company’s financial position, results of operations, comprehensive loss and cash flows for the periods indicated. The preparation of financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”) requires management to make assumptions and estimates that affect, among other things, (i) reported amounts of assets and liabilities; (ii) disclosure of contingent assets and liabilities at the date of the consolidated financial statements; and (iii) reported amounts of revenues and expenses during the reporting period. The results of operations for the three and nine months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the entire fiscal year or any future period.

The Company currently develops proprietary sustained-release drug products for the treatment of chronic eye diseases. The Company’s approved products and product candidates 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. Durasert™ three-year non-erodible fluocinolone acetonide (“FA”) insert for posterior segment uveitis (“Durasert three-year uveitis”) (formerly known as Medidur™), the Company’s lead product candidate, is in pivotal Phase 3 clinical trials, and ILUVIEN® for diabetic macular edema (“ILUVIEN”), the Company’s most recent out-licensed product, is sold directly in the U.S. and three European Union (“EU”) countries. Retisert®, which was approved by the FDA for the treatment of posterior segment uveitis, is sold by Bausch & Lomb Incorporated (“Bausch & Lomb”). The Company’s development programs are focused primarily on developing sustained release products that utilize its Durasert technology platform to deliver approved drugs to treat chronic diseases. The Company’s strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

Durasert three-year uveitis, the Company’s most advanced development product candidate, is designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (“posterior segment uveitis”) for three years from a single administration. Injected into the eye in an office visit, this product candidate is a tiny micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained basis. The Company is developing Durasert three-year uveitis independently.

The first of two Phase 3 clinical trials investigating Durasert three-year uveitis met its primary efficacy endpoint of prevention of recurrence of disease through six months with high statistical significance ($p < 0.001$, intent to treat analysis) and with safety data consistent with the known effects of ocular corticosteroid use. The same high statistical significance for efficacy and encouraging safety results were maintained through 12 months of follow-up. Due to the high level of statistical significance achieved, the Company plans to file its EU marketing approval application (“MAA”) based on data from the first Phase 3 clinical trial, rather than two clinical trials. The Company expects to file the MAA in June 2017. The second Phase 3 clinical trial completed its target enrollment of 150 patients at the end of September 2016. This clinical trial has the same clinical trial design and the same endpoint as the first Phase 3 clinical trial, and a read-out of its top-line results is expected in June 2017. Assuming favorable results, the Company plans to file a new drug application (“NDA”) with the FDA in the fourth quarter of calendar 2017. The Company’s new Durasert three-year uveitis inserter with a smaller diameter needle, and original inserter with a slightly larger diameter needle and simpler mechanism, were evaluated in a utilization study that will be filed in both the MAA and NDA. Both inserters met their primary endpoint of ease of intravitreal administration.

ILUVIEN is an injectable, sustained-release micro-insert that provides three years of treatment of diabetic macular edema from a single injection. ILUVIEN is based on the same technology as the Durasert three-year uveitis

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insert, and delivers the same corticosteroid, FA. ILUVIEN was developed in collaboration with, and is licensed to and sold by, Alimera Sciences, Inc. (“Alimera”). 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 has been sold directly in the United Kingdom (“U.K.”) and Germany since June 2013 and in the U.S. and Portugal since 2015, and also has marketing approvals in 14 other European countries. Alimera has sublicensed distribution, regulatory and reimbursement matters for ILUVIEN in Australia and New Zealand, Canada, Italy, Spain and numerous countries in the Middle East.

The Company’s FDA-approved Retisert is an implant that provides sustained treatment of posterior segment uveitis for 30 months. Administered in a surgical procedure, Retisert delivers the same corticosteroid as the Durasert three-year non-erodible insert, but in a larger dose. Retisert was co-developed with, and is licensed to, Bausch & Lomb, and the Company receives royalties from its sales.

The Company’s development programs are focused primarily on developing sustained release drug products using its proven Durasert technology platform to deliver small molecule drugs to treat uveitis, wet age-related macular degeneration (“AMD”), osteoarthritis and other diseases. A sustained-release surgical implant delivering a corticosteroid to treat pain associated with severe knee osteoarthritis that was jointly developed by the Company and Hospital for Special Surgery is currently being evaluated in an investigator-sponsored safety and tolerability study. The Company has minimized further development work of its Tethadur™ technology platform designed to deliver large molecules, such as biologics, both locally and systemically, in order to focus its resources on leveraging its proven Durasert technology for delivery of small molecules.

The Company has financed its operations primarily from sales of equity securities and the receipt of license fees, milestone payments, research and development funding and royalty income from its collaboration partners. The Company has a history of operating losses and, to date, has not had significant recurring cash inflows from revenue. The Company believes that its cash, cash equivalents and marketable securities of \$15.4 million at March 31, 2017, together with subsequent cash proceeds received from additional utilization of its at-the-market (“ATM”) equity program (refer to Note 8) and from existing collaboration agreements, will enable the Company to maintain its current and planned operations (including its two Durasert three-year uveitis Phase 3 clinical trials) through approximately the third quarter of fiscal 2018. This estimate excludes any potential receipts under the Alimera agreement. In order to extend the Company’s ability to fund operations beyond the third quarter of fiscal 2018, management’s plans include reducing or deferring operating expenses and/or accessing additional equity financing from the sale of its common stock through its ATM program or other financing transactions. The timing and extent of the Company’s implementation of these plans is expected to depend on the amount and timing of cash receipts from Alimera’s commercialization of ILUVIEN, proceeds from any future collaboration or other agreements and/or proceeds from any financing transactions. There is no assurance that the Company will receive significant, if any, revenues from Alimera’s commercialization of ILUVIEN or financing from any other sources.

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 the adoption of this standard will have on its consolidated 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 annual periods ending after December 15, 2016, and interim periods thereafter. As a result, ASU 2014-15 will become effective for the annual period ending June 30, 2017, and interim periods thereafter. The Company is evaluating the impact the adoption of this standard will have on its consolidated financial statements.

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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. As a result, ASU 2016-02 will become effective on July 1, 2019. 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 evaluating the impact the adoption of this standard will have on its consolidated 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. As a result, ASU 2016-09 will become effective on July 1, 2017. The Company is evaluating the impact the amendment of this guidance will have 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) from 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 (as defined) on sales of each licensed product (including ILUVIEN) by such sublicensee 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 generally 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. In instances when payments are received and subject to a contingency, revenue is deferred until such contingency is resolved. See Note 10 regarding net profit share receipts subject to arbitration proceedings.

Revenue under the Alimera Agreement totaled \$290,000 and \$35,000 for the three months ended March 31, 2017 and 2016, respectively, and \$324,000 and \$226,000 for the nine months ended March 31, 2017 and 2016, respectively. In addition to patent fee reimbursements in both periods, the Company received \$252,000 of net profits in the three and nine months ended March 31, 2017 and earned \$157,000 of non-royalty sublicense consideration during the nine months ended March 31, 2016.

Pfizer

In June 2011, the Company and Pfizer, Inc. (“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 injected into the subconjunctiva 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 provide Pfizer options under various circumstances for an exclusive, worldwide license to develop and commercialize the Latanoprost Product.

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The estimated selling price of the combined deliverables under the Restated Pfizer Agreement of \$6.7 million has been partially recognized to date as collaborative research and development revenue over the estimated performance period using the proportional performance method with costs associated with developing the Latanoprost Product reflected in operating expenses in the period in which they have been incurred. No collaborative research and development revenue was recorded during each of the three and nine month periods ended March 31, 2016.

On October 25, 2016, the Company notified Pfizer that it had discontinued development of the Latanoprost Product, which provided Pfizer a 60-day option to acquire a worldwide license in return for a \$10.0 million payment and potential sales-based royalties and development, regulatory and sales performance milestone payments. Pfizer did not exercise its option and the Restated Pfizer Agreement automatically terminated on December 26, 2016. The remaining deferred revenue balance of \$5.6 million was recognized as revenue in the three month period ended December 31, 2016. Provided that the Company does not conduct any research and development of the Latanoprost Product through calendar 2017, the Company retains the right thereafter to develop and commercialize the Latanoprost Product on its own or with a partner. By letter agreement effective as of April 11, 2017, Pfizer officially waived that restriction.

Pfizer owned approximately 5.2% of the Company's outstanding common stock at March 31, 2017.

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. Royalty income totaled \$218,000 and \$274,000 for the three months ended March 31, 2017 and 2016, respectively, and \$730,000 and \$944,000 for the nine months ended March 31, 2017 and 2016, respectively. Accounts receivable from Bausch & Lomb totaled \$220,000 at March 31, 2017 and \$288,000 at June 30, 2016.

OncoSil Medical

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with OncoSil Medical UK Limited (f/k/a Enigma Therapeutics Limited), a wholly owned subsidiary of OncoSil Medical Ltd ("OncoSil") 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. OncoSil 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 2016. 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 OncoSil 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 OncoSil agreement in either of the three-month periods ended March 31, 2017 and 2016 and \$100,000 of revenue for each of the nine-month periods ended March 31, 2017 and 2016. As of March 31, 2017, no deferred revenue was recorded for this agreement.

Evaluation Agreements

The Company from time to time enters into funded agreements to evaluate the potential use of its technology systems for sustained release of third party drug candidates in the treatment of various diseases. Consideration received is generally recognized as revenue over the term of the feasibility study agreement. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the evaluation agreement. Revenues under evaluation agreements totaled \$80,000 and \$8,000 for the three-months ended March 31, 2017 and 2016, respectively, and \$91,000 and \$25,000 for the nine months ended March 31, 2017 and 2016, respectively. Deferred revenue for these agreements totaled \$120,000 and \$11,000 at March 31, 2017 and June 30, 2016, respectively.

3. Intangible Assets

The reconciliation of intangible assets for the nine months ended March 31, 2017 and for the year ended June 30, 2016 was as follows (in thousands):

	<u>Nine Months Ended March 31, 2017</u>	<u>Year Ended June 30, 2016</u>
Patented technologies		
Gross carrying amount at beginning of period	\$ 36,196	\$ 39,710
Foreign currency translation adjustments	(1,364)	(3,514)
Gross carrying amount at end of period	34,832	36,196
Accumulated amortization at beginning of period	(35,094)	(37,785)
Amortization expense	(542)	(756)
Foreign currency translation adjustments	1,344	3,447
Accumulated amortization at end of period	(34,292)	(35,094)
Net book value at end of period	<u>\$ 540</u>	<u>\$ 1,102</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 \$180,000 and \$187,000 for the three months ended March 31, 2017 and 2016, respectively, and \$542,000 and \$569,000 for the nine months ended March 31, 2017 and 2016, respectively. The carrying value of intangible assets at March 31, 2017 of \$540,000 (approximately \$397,000 attributable to the Durasert technology and \$143,000 attributable to the Tethadur technology) is expected to be amortized on a straight-line basis over the remaining estimated useful life of 9 months.

4. Marketable Securities

The amortized cost, unrealized loss and fair value of the Company's available-for-sale marketable securities at March 31, 2017 and June 30, 2016 were as follows (in thousands):

	<u>March 31, 2017</u>		
	<u>Amortized Cost</u>	<u>Unrealized Loss</u>	<u>Fair Value</u>
Corporate bonds	\$ 500	\$ —	\$ 500
Commercial paper	1,999	—	1,999
Total marketable securities	<u>\$ 2,499</u>	<u>\$ —</u>	<u>\$ 2,499</u>
	<u>June 30, 2016</u>		
	<u>Amortized Cost</u>	<u>Unrealized Loss</u>	<u>Fair Value</u>
Corporate bonds	\$ 5,999	\$ (2)	\$ 5,997
Commercial paper	7,682	—	7,682
Total marketable securities	<u>\$ 13,681</u>	<u>\$ (2)</u>	<u>\$ 13,679</u>

During the nine months ended March 31, 2017, \$5.1 million of marketable securities were purchased and \$16.2 million of such securities matured. At March 31, 2017, the marketable securities had maturities ranging from 4 days to 1.3 months, with a weighted average maturity of 18 days.

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, 2017, substantially all of the Company’s interest-bearing cash equivalent balances were concentrated in one U.S. Government money market fund that has investments consisting primarily of U.S. Government Agency debt, U.S. Treasury Repurchase Agreements and U.S. Government Agency Repurchase Agreements. At June 30, 2016, substantially all of the Company’s interest-bearing cash equivalent balances were concentrated in one institutional money market fund that had investments consisting primarily of certificates of deposit, commercial paper, time deposits, U.S. Government Agency debt, treasury bills and U.S. 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, 2017 and June 30, 2016 by valuation hierarchy (in thousands):

	March 31, 2017			
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 10,985	\$ 10,985	\$ —	\$ —
Marketable securities				
Corporate bonds	500	500	—	—
Commercial paper	1,999	—	1,999	—
	<u>\$ 13,484</u>	<u>\$ 11,485</u>	<u>\$ 1,999</u>	<u>\$ —</u>

	June 30, 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	\$ 13,856	\$ 12,957	\$ 899	\$ —
Marketable securities				
Corporate bonds	5,997	4,596	1,401	—
Commercial paper	7,682	—	7,682	—
	<u>\$ 27,535</u>	<u>\$ 17,553</u>	<u>\$ 9,982</u>	<u>\$ —</u>

6. Accrued Expenses

Accrued expenses consisted of the following at March 31, 2017 and June 30, 2016 (in thousands):

	March 31, 2017	June 30, 2016
Clinical trial costs	\$ 2,166	\$ 1,678
Personnel costs	1,052	1,314
Professional fees	715	535
Other	10	56
	<u>\$ 3,943</u>	<u>\$ 3,583</u>

7. Restructuring

In July 2016, the Company announced its plan to consolidate its research and development activities in its U.S. facility. Following employee consultations under local U.K. law, the Company determined to close its U.K. research facility and terminated the employment of its U.K. employees. The U.K. facility lease, set to expire on August 31, 2016, was extended through November 30, 2016 to facilitate an orderly transition and the required restoration of the premises. A summary reconciliation of the restructuring costs is as follows (in thousands):

	Balance at June 30, 2016	Charged to Expense	Payments	Balance at March 31, 2017
Termination benefits	\$ 118	\$ 273	\$ (391)	\$ —
Facility closure	40	73	(113)	—
Other	29	126	(155)	—
	<u>\$ 187</u>	<u>\$ 472</u>	<u>\$ (659)</u>	<u>\$ —</u>

The Company recorded approximately \$472,000 of restructuring costs during the nine months ended March 31, 2017. These costs consisted of (i) \$273,000 of additional employee severance for discretionary termination benefits upon notification of the affected employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*; and (ii) \$199,000 of professional fees, travel and lease extension costs.

In addition, for the nine months ended March 31, 2017, the Company recorded \$99,000 of non-cash stock-based compensation expense in connection with the extension of the exercise period for all vested stock options held by the U.K. employees at July 31, 2016 and a \$133,000 credit to stock-based compensation expense to account for forfeitures of all non-vested stock options at that date.

The Company has paid all of the restructuring costs associated with the plan of consolidation as of March 31, 2017.

8. Stockholders' Equity

In February 2017, the Company entered into an ATM program pursuant to which, under its Form S-3 shelf registration statement, 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 \$20.0 million. The Company will pay 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 Australian Securities Exchange (the "ASX") listing rules, as defined, limiting the number of shares the Company may issue in any 12-month period without stockholder approval, as well as other applicable rules and regulations of the ASX and the NASDAQ Global Market. During the three months ended March 31, 2017, the Company incurred approximately \$223,000 of legal, accounting and other costs to establish and activate the ATM program.

During March 2017, the Company sold 1,411,686 shares of common stock under the ATM program at a weighted average price of \$1.74 per share for gross proceeds of \$2.45 million. Share issue costs, including sales agent commissions, totaled \$76,000.

From April 1, 2017 through May 4, 2017, the Company sold an additional 3,600,007 shares of common stock at a weighted average price of \$1.74 per share for gross proceeds of approximately \$6.3 million under its ATM program. On account of the ASX listing rules noted above, and after aggregating all of the shares sold under the ATM program from March 1, 2017 through May 4, 2017, the Company may issue approximately 100,000 additional shares of common stock without obtaining stockholder approval of any further issuances of common shares during the ensuing 12-month period (see Note 12).

Warrants to Purchase Common Shares

The following table provides a reconciliation of warrants to purchase common stock for the nine months ended March 31, 2017 and 2016:

	Nine Months Ended March 31,			
	2017		2016	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	623,605	\$ 2.50	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>623,605</u>	<u>\$ 2.50</u>

The outstanding warrants at March 31, 2017 have an expiration date of August 7, 2017.

2016 Long Term Incentive Plan

The Company's shareholders approved the adoption of the 2016 Incentive Plan on December 12, 2016 (the Adoption Date), which was approved by the Board of Directors on October 3, 2016 and subsequently amended by the Compensation Committee of the Board of Directors on February 3, 2017 to change the name of the plan to the 2016 Long Term Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of stock options and other awards to employees and directors of, and consultants and advisors to, the Company. The 2016 Plan provides for the issuance of up to 3,000,000 shares of common stock reserved for issuance under the 2016 Plan plus, as of December 31, 2016, (i) 489,241 shares of common stock that were previously available for grant under the pSivida Corp. 2008 Incentive Plan, as amended (the "2008 Plan") and (ii) up to 6,257,891 shares of common stock that would otherwise have become available for grant under the 2008 Plan as a result of subsequent termination or forfeiture of awards under the 2008 Plan.

During the three months ended March 31, 2017, no equity awards were made under the 2016 Plan and 30,200 options that were forfeited under the 2008 Plan became available for grant under the 2016 Plan. At March 31, 2017, a total of 3,519,441 shares were available for grant under the 2016 Plan.

2008 Plan

The 2008 Plan provides for the issuance of stock options and other stock awards to directors, employees and consultants. As of December 12, 2016, which was the effective date of the 2016 Plan, there were 336,741 shares available for grant of future awards under the 2008 Plan, which were carried over to the 2016 Plan. Effective as of such date, the Compensation Committee terminated the 2008 Plan in all respects, other than with respect to previously-granted awards, and no additional stock options and other stock awards will be issued under the 2008 Plan. Subsequent to December 12, 2016 and through March 31, 2017, an additional 182,700 stock options under the 2008 Plan were forfeited and became available for grant under the 2016 Plan. The following table provides a reconciliation of stock option activity under the 2008 Plan for the nine months ended March 31, 2017:

	<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, 2016	4,981,421	\$ 3.60		
Granted	1,535,300	3.24		
Exercised	(84,080)	1.18		
Forfeited	(484,950)	4.02		
Outstanding at March 31, 2017	<u>5,947,691</u>	<u>\$ 3.50</u>	<u>4.59</u>	<u>\$ 130</u>
Outstanding at March 31, 2017 - vested or unvested and expected to vest	<u>5,826,821</u>	<u>\$ 3.50</u>	<u>4.51</u>	<u>\$ 130</u>
Exercisable at March 31, 2017	<u>4,100,657</u>	<u>\$ 3.53</u>	<u>2.62</u>	<u>\$ 130</u>

During the nine months ended March 31, 2017, the Company granted 1,405,300 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 vesting over 3 years. All option grants have a 10-year term. The weighted-average grant date fair value of these options was \$1.95 per share. A total of 964,503 options vested during the nine months ended March 31, 2017. 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 under the 2008 Plan during the nine months ended March 31, 2017 based on the following key assumptions:

Option life (in years)	5.50 - 6.25
Stock volatility	70% - 72%
Risk-free interest rate	1.23% - 2.08%
Expected dividends	0%

Inducement Option Grant

In connection with the September 15, 2016 hire of the Company's President and CEO, the Company granted, as an inducement award, 850,000 options to purchase common stock with ratable vesting over 4 years, an exercise price of \$3.63 per share and a 10-year term. Although the stock options were not awarded under the 2008 Plan, the stock options are subject to and governed by the terms and conditions of the 2008 Plan. The grant date fair value of \$0.84 per share, measured at the Adoption Date, was determined based upon assumptions of an option life of 6.25 years, historical stock volatility of 70%, a risk-free interest rate of 2.13% and expected dividends of 0%.

Restricted Stock Units

During the nine months ended March 31, 2017, the Company issued 700,000 market-based Restricted Stock Units ("market-based RSUs") to two employees, which included 500,000 as an inducement grant to the Company's

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President and CEO, and 200,000 issued under the 2008 Plan. The market-based RSUs vest based upon a relative percentile rank of the 3-year change in the closing price of the Company's common stock compared to that of the companies that make up the NASDAQ Biotechnology Index ("NBI"). The Company estimated the fair value of the market-based RSUs using a Monte Carlo valuation model on the respective dates of grant, using the following key assumptions:

Grant date stock price	\$1.91 - \$3.63
Stock volatility	50% - 60%
Risk-free interest rate	0.87% - 0.98%
Expected dividends	0%

The weighted-average grant date fair value of the market-based RSUs was \$1.35 per share.

Stock-Based Compensation Expense

The Company's statements of comprehensive loss included total compensation expense from stock-based payment awards for the three and nine months ended March 31, 2017 and 2016, as follows (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2017	2016	2017	2016
Compensation expense included in:				
Research and development	\$ 267	\$ 180	\$ 803	\$ 521
General and administrative	377	481	971	1,028
	<u>\$ 644</u>	<u>\$ 661</u>	<u>\$ 1,774</u>	<u>\$ 1,549</u>

In connection with termination benefits provided to the Company's former Chief Executive Officer, the vesting of certain options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended through September 14, 2017, and all remaining non-vested options were forfeited. Additionally, in connection with the U.K. restructuring, the exercise period of all vested options held by the former U.K. employees was extended through June 30, 2017 and all non-vested options were forfeited. These option modifications and forfeitures were accounted for in the quarter ended September 30, 2016, the net effect of which resulted in an approximate \$274,000 increase of stock-based compensation expense included in general and administrative expense and an approximate \$35,000 reduction of stock-based compensation expense included in research and development expense for the nine months ended March 31, 2017 in the table above.

In connection with termination benefits provided to the Company's former Vice President, Corporate Affairs and General Counsel, the vesting of certain options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended through June 28, 2018 and all remaining non-vested options were forfeited. The option modification and forfeitures were accounted for in the quarter ended December 31, 2016, the net effect of which resulted in an approximate \$117,000 reduction of stock-based compensation expense included in general and administrative expense for the nine months ended March 31, 2017 in the table above.

At March 31, 2017, there was approximately \$3.4 million of unrecognized compensation expense related to unvested stock options under the 2008 Plan, the inducement stock option grant to the Company's President and CEO and the market-based RSUs, which is expected to be recognized as expense over a weighted-average period of approximately 2.1 years.

9. 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 \$34,000 for the three months ended March 31, 2016 and \$117,000 for the nine months ended March 31, 2016. The tax benefits for the three and nine months ended March 31, 2016 represented earned foreign research and development tax credits, which were not available to the Company in fiscal 2017.

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For the three and nine months ended March 31, 2017 and 2016, the Company had no significant unrecognized tax benefits. At March 31, 2017 and June 30, 2016, the Company had no accrued penalties or interest related to uncertain tax positions.

10. Commitments and Contingencies

Operating Leases

The Company leases approximately 13,650 square feet of combined office and laboratory space in Watertown, Massachusetts under a lease with a term from March 2014 through April 2019, with a five-year renewal option at market rates. The Company provided a cash-collateralized \$150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease. 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.

In addition, the Company occupied approximately 2,200 square feet of laboratory and office space in Malvern, U.K. under a lease with a term that was to expire on August 31, 2016. The lease term was extended through November 2016 to facilitate an orderly transition of the closure of a substantial portion of the U.K. facility in connection with the consolidation of the Company's research and development activities in its U.S. laboratory facilities. The Company has entered into a new lease in Malvern for 420 square feet of office space under a 3-year lease term effective December 1, 2016, with termination rights by the Company upon 30 days advance notice.

Legal Proceedings

In December 2014, the Company exercised its right under the Alimera Agreement to conduct an audit by an independent accounting firm of Alimera's commercialization reporting for ILUVIEN for calendar 2014. In April 2016, the independent accounting firm issued its report, which concluded that Alimera under-reported net profits payable to the Company for 2014 by \$136,000. In June 2016, Alimera remitted \$354,000 to the Company, which consisted of the under-reported net profits plus interest and reimbursement of the audit costs of \$204,000. In July 2016, Alimera filed a demand for arbitration with the American Arbitration Association ("AAA") in Boston, Massachusetts to dispute the audit findings and requested a full refund of the \$354,000 previously paid to the Company. Pending the arbitration outcome, \$136,000 of net profits participation had been recorded as deferred revenue and the remaining \$218,000 as accrued expenses at each of March 31, 2017 and June 30, 2016.

On May 3, 2017, the parties reached a settlement of the arbitration, which was dismissed with prejudice. As a result of the settlement, the \$136,000 of net profits became fixed and determinable, while the gain contingency resulting from reimbursement of the audit costs of \$204,000 became resolved. Accordingly, these transactions will be recognized in the fourth quarter of fiscal 2017.

The Company is subject to various other 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.

11. Net Loss per Share

Basic net loss per share is computed by dividing the net loss 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. Potentially dilutive shares were not included in the calculation of diluted net loss per share for each of the three and nine months ended March 31, 2017 and 2016 as their inclusion would be anti-dilutive.

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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>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Options outstanding	6,797,691	5,071,421	6,797,691	5,071,421
Warrants outstanding	623,605	623,605	623,605	623,605
RSUs outstanding	700,000	—	700,000	—
	<u>8,121,296</u>	<u>5,695,026</u>	<u>8,121,296</u>	<u>5,695,026</u>

12. Subsequent Events

On May 4, 2017, the Company filed a preliminary proxy statement with the SEC in connection with a special meeting of stockholders to be held on June 27, 2017. The purpose of the special meeting will be to seek (i) stockholder ratification of the issuance of approximately 5.1 million shares of common stock under the ATM program pursuant to ASX Listing Rule 7.4 to refresh the Company's capacity to issue shares of common stock without prior stockholder approval pursuant to ASX Listing Rule 7.1; and (ii) stockholder approval of an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of authorized shares of common stock from 60,000,000 shares to 120,000,000 shares.

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 (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- the sufficiency of our cash and cash equivalents to fund our operations through approximately the third quarter of fiscal 2018;
- our ability to obtain additional capital in sufficient amounts and on terms acceptable to us, and the consequences of failing to do so;
- future operating expenses and capital expenditures;
- our expectations regarding the timing and design of our clinical development plans;
- the timing of regulatory filings, both in the United States of America (“U.S.”) and the European Union (“EU”)
- our expectation to submit a marketing approval application (“MAA”) to the EU for Durasert™ three-year non-erodible fluocinolone acetonide (“FA”) insert for posterior segment uveitis (“Durasert three-year uveitis”) (formerly known as Medidur™) in June 2017;
- our expectation to submit a new drug application (“NDA”) to the U.S. Food and Drug Administration (“FDA”) for Durasert three-year uveitis in the fourth quarter of calendar 2017;
- the implication of results from pre-clinical and clinical trials and our other research activities;
- our intentions regarding our research into the use and application of our Durasert and Tethadur™ technology platforms;
- the impact of changes in foreign exchange rates for the currencies in which we operate on our operating expenses and stockholders’ equity;
- our expectation that we will continue to incur significant expenses and that our operating losses and our net cash outflows to fund operations will continue for the foreseeable future;
- the potential advantages of our product candidates and technologies;
- the scope and duration of intellectual property protection; and
- the effect of legal and regulatory developments.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to 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 needed capital; fluctuations in our operating results; further impairment of our intangible assets; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema (“ILUVIEN”), which depends on Alimera’s ability to continue as a going concern and the effect of pricing and reimbursement decisions on sales of ILUVIEN; safety and efficacy results of the second Durasert three-year uveitis Phase 3 clinical trial and the number of clinical trials and data required for the Durasert three-year uveitis marketing approval applications in the U.S. and EU; our ability to file and the timing of filing and acceptance of the Durasert three-year uveitis marketing approval applications in the U.S. and EU; our ability to use data in a U.S. NDA from clinical trials outside the U.S.; maintenance of European orphan drug designation for Durasert three-year uveitis; our ability to successfully commercialize Durasert three-year uveitis, if approved; potential off-label sales of ILUVIEN for uveitis; consequences of FA side effects; potential declines in

Retisert® royalties; our ability to develop Tethadur to successfully deliver large biologic molecules and develop products using it; efficacy and our future development of an implant to treat severe osteoarthritis; 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; our dependence on contract research organizations (“CROs”), vendors and investigators; 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; effects of the potential U.K. exit from the EU; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission (the “SEC”). You should read and interpret any forward-looking statements in light of 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 dates 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 currently develop proprietary sustained-release pharmaceutical products for the treatment of chronic eye diseases. Our approved products and our product candidates 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 FDA for treatment of back-of-the-eye diseases. Durasert three-year uveitis, our lead product candidate, is in pivotal Phase 3 clinical trials, and ILUVIEN, our most recent out-licensed product, is sold in the U.S. and three EU countries. Retisert, which was approved by the FDA for the treatment of posterior segment uveitis, is sold by Bausch & Lomb Incorporated (“Bausch & Lomb”). Our product development programs are focused primarily on utilizing our Durasert technology platform to deliver drugs to treat chronic diseases. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaborations and license agreements.

Durasert three-year uveitis, our most advanced development product candidate, is designed to treat chronic non-infectious uveitis affecting the posterior segment of the eye (“posterior uveitis”) for three years from a single administration. Injected into the eye in an office visit, this product candidate is a tiny micro-insert that delivers a micro-dose of a corticosteroid, FA, to the back of the eye on a sustained basis. We are developing Durasert three-year uveitis independently.

The first of two Phase 3 clinical trials investigating Durasert three-year uveitis met its primary efficacy endpoint of prevention of recurrence of disease through six months with high statistical significance ($p < 0.001$, intent to treat analysis) and with safety data consistent with the known effects of ocular corticosteroid use. The same high statistical significance for efficacy and encouraging safety results were maintained through 12 months of follow-up. Due to the high level of statistical significance achieved, we plan to file our EU MAA based on data from the first Phase 3 clinical trial, rather than two clinical trials. We expect to file the MAA in June 2017. The second Phase 3 clinical trial investigating Durasert three-year uveitis completed its target enrollment of 150 patients at the end of September 2016. This clinical trial has the same clinical trial design and the same endpoint as the first Phase 3 clinical trial, and a read-out of its top-line results is expected in June 2017. Assuming favorable results, we plan to file an NDA with the FDA in the fourth quarter of calendar 2017. Our new Durasert three-year uveitis inserter with a smaller diameter needle, and original inserter with a slightly larger diameter needle and simpler mechanism, were evaluated in a utilization study that will be filed in both the MAA and NDA. Both inserters met their primary endpoint of ease of intravitreal administration.

ILUVIEN is an injectable, sustained-release micro-insert that provides three years of treatment of diabetic macular edema from a single injection. ILUVIEN is based on the same technology as the Durasert three-year uveitis insert, and delivers the same corticosteroid, FA. ILUVIEN was developed in collaboration with, and is licensed to and sold by Alimera Sciences, Inc. (“Alimera”). 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 has been sold directly in the United Kingdom and Germany since June 2013 and in the U.S. and Portugal since 2015, and also has marketing approvals in 14 other European countries. Distribution, regulatory and reimbursement matters for ILUVIEN in Australia and New Zealand, Canada, Italy, Spain and numerous countries in the Middle East have been sublicensed.

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In the event that Alimera sublicenses commercialization in any country, we are entitled to 20% of royalties (as defined) on sales of each licensed product by such sublicensee and 33% of non-royalty consideration received by Alimera less certain permitted deductions. We are also entitled to reimbursement of certain patent maintenance costs with respect to the patents licensed to Alimera.

Our FDA-approved Retisert is an implant that provides sustained release treatment of posterior segment uveitis for 30 months. Administered in a surgical procedure, Retisert delivers the same corticosteroid as the Durasert three-year uveitis insert, but in a larger dose. Retisert was co-developed with, and licensed to, Bausch & Lomb, and we receive royalties from its sales.

Our development programs are focused primarily on developing sustained release drug products using our proven Durasert technology platform to deliver small molecule drugs to treat uveitis, wet age-related macular degeneration (“AMD”), osteoarthritis and other diseases. A sustained-release surgical implant delivering a corticosteroid to treat pain associated with severe knee osteoarthritis that was jointly developed by the Company and Hospital for Special Surgery is currently being evaluated in an investigator-sponsored safety and tolerability study. We have minimized further development work of our Tethadur technology platform designed to deliver large molecules, such as biologics, both locally and systemically, in order to focus our resources on leveraging our proven Durasert technology for delivery of small molecules.

Durasert™, 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 fiscal year ended June 30, 2016 (the “2016 Annual Report”), 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 2016 Annual Report.

Results of Operations**Three Months Ended March 31, 2017 Compared to Three Months Ended March 31, 2016:**

	Three Months Ended March 31,		Change	
	2017	2016	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	\$ 372	\$ 50	\$ 322	644%
Royalty income	218	274	(56)	(20)%
Total revenues	<u>590</u>	<u>324</u>	<u>266</u>	<u>82%</u>
Operating expenses:				
Research and development	3,324	3,074	250	8%
General and administrative	2,426	2,346	80	3%
Total operating expenses	<u>5,750</u>	<u>5,420</u>	<u>330</u>	<u>6%</u>
Loss from operations	(5,160)	(5,096)	(64)	(1)%
Interest and other income	20	21	(1)	(5)%
Loss before income taxes	(5,140)	(5,075)	(65)	(1)%
Income tax benefit	—	34	(34)	(100)%
Net loss	<u><u>\$ (5,140)</u></u>	<u><u>\$ (5,041)</u></u>	<u><u>\$ (99)</u></u>	<u><u>(2)%</u></u>

Revenues

Collaborative research and development revenues totaled \$372,000 for the three months ended March 31, 2017 compared to \$50,000 for the three months ended March 31, 2016. This increase was attributable primarily to \$252,000 of net profits received in the current quarter under our Alimera collaboration agreement and \$80,000 recognized from a feasibility study agreement entered into in the current quarter.

We are entitled to share in the net profits, on a quarter-by-quarter and country-by-country basis, from sales of ILUVIEN by our licensee, Alimera, and are also entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera wherever it sublicenses commercialization of ILUVIEN. We do not know when and if we will receive future net profit payments with respect to any country where Alimera sells ILUVIEN or payments with respect to countries where Alimera sublicenses the sale of ILUVIEN.

Royalty income from sales of Retisert decreased by \$56,000, or 20%, to \$218,000 for the three months ended March 31, 2017 compared to \$274,000 for the three months ended March 31, 2016. We do not expect Retisert royalty income to increase significantly, and it may decline further.

Research and Development

Research and development expenses increased by \$250,000, or 8%, to \$3.3 million for the three months ended March 31, 2017 from \$3.1 million for the same quarter a year earlier, attributable primarily to increases of approximately \$390,000 of U.S.-based personnel and related costs, including stock-based compensation, which included the August 2016 hire of our Chief Medical Officer and a significant increase in fiscal 2017 employee stock option grants, and \$370,000 of professional services related primarily to our Durasert three-year uveitis Phase 3 clinical development program and planned MAA and NDA filings, partially offset by decreases of approximately \$315,000 of costs of our U.K. subsidiary resulting primarily from the previously announced U.K. restructuring and \$170,000 of CRO costs for the Durasert three-year uveitis clinical development program. We expect to continue to incur significant research and development expense for Durasert three-year uveitis during the remainder of fiscal 2017 and in future periods until completion of its clinical development and regulatory approval processes.

General and Administrative

General and administrative expenses increased by \$80,000, or 3%, to \$2.4 million for the three months ended March 31, 2017 from \$2.3 million for the same period in the prior year, attributable primarily to increased professional services fees.

Income Tax Benefit

Income tax benefit of \$0 for the three months ended March 31, 2017 compared to \$34,000 for the three months ended March 31, 2016. Refundable foreign research and development tax credits were not available for the three months ended March 31, 2017 as a result of the consolidation of our research and development activities in the U.S. during the quarter ended September 30, 2016.

Nine Months Ended March 31, 2017 Compared to Nine Months Ended March 31, 2016:

	Nine Months Ended March 31,		Change	
	2017	2016	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	\$ 6,108	\$ 372	\$ 5,736	1,542%
Royalty income	730	944	(214)	(23)%
Total revenues	<u>6,838</u>	<u>1,316</u>	<u>5,522</u>	<u>420%</u>
Operating expenses:				
Research and development	10,667	10,277	390	4%
General and administrative	8,611	6,357	2,254	35%
Total operating expenses	<u>19,278</u>	<u>16,634</u>	<u>2,644</u>	<u>16%</u>
Loss from operations	(12,440)	(15,318)	2,878	19%
Interest and other income	71	41	30	73%
Loss before income taxes	<u>(12,369)</u>	<u>(15,277)</u>	<u>2,908</u>	<u>19%</u>
Income tax benefit	—	117	(117)	(100)%
Net loss	<u><u>\$(12,369)</u></u>	<u><u>\$(15,160)</u></u>	<u><u>\$ 2,791</u></u>	<u><u>18%</u></u>

Revenues

Collaborative research and development revenues totaled \$6.1 million for the nine months ended March 31, 2017 compared to \$372,000 for the nine months ended March 31, 2016. This increase was attributable primarily to \$5.6 million of revenue recognized upon the termination of the Restated Pfizer Agreement in December 2016 and a \$98,000 increase in revenues earned under our Alimera collaboration agreement, which consisted primarily of \$252,000 of ILUVIEN net profits received in the quarter ended March 31, 2017, partially offset by \$157,000 of non-royalty sublicense consideration earned in the first quarter of the prior fiscal year.

Royalty income from sales of Retisert decreased by \$214,000, or 23%, to \$730,000 for the nine months ended March 31, 2017 compared to \$944,000 for the nine months ended March 31, 2016.

Research and Development

Research and development expenses increased by \$390,000, or 4%, to \$10.7 million for the nine months ended March 31, 2017 from \$10.3 million for the prior year-to-date period. This increase was attributable primarily to approximately (i) \$855,000 of professional services related primarily to our Duraseret three-year uveitis Phase 3 clinical development program and planned MAA and NDA filings, (ii) \$555,000 of U.S. personnel and related costs due primarily to the August 2016 hire of our Chief Medical Officer and (iii) \$430,000 of U.S. stock-based compensation, partially offset by decreases of approximately (i) \$810,000 of CRO costs for our Duraseret three-year uveitis clinical development, (ii) \$405,000 of U.K. costs related to the effect of the U.K. restructuring; and (iii) \$265,000 of U.S. pre-clinical studies and other third party research costs related primarily to prior year studies of potential tyrosine kinase inhibitor (“TKI”) compounds and purchases of lab and clinical supplies for our Duraseret three-year uveitis clinical development program.

General and Administrative

General and administrative expenses increased by \$2.3 million, or 35%, to \$8.6 million for the nine months ended March 31, 2017 from \$6.4 million for the same period in the prior year, attributable primarily to approximately \$1.5 million of severance costs and professional fees associated with our CEO transition and the elimination of the position of Vice President, Corporate Affairs and General Counsel, as well as an approximate \$500,000 increase in other professional fees, due primarily to patent legal fees and legal fees related to the arbitration proceedings with Alimera, and an approximate \$270,000 increase in other personnel and related costs.

Income Tax Benefit

Income tax benefit of \$0 for the nine months ended March 31, 2017 compared to \$117,000 for the nine months ended March 31, 2016. Refundable foreign research and development tax credits were not available for the nine months ended March 31, 2017 as a result of the consolidation of our research and development activities in the U.S. during the quarter ended September 30, 2016.

Liquidity and Capital Resources

Our fiscal 2017 year-to-date operations were financed primarily from existing capital resources at June 30, 2016. At March 31, 2017, our principal sources of liquidity were cash, cash equivalents and marketable securities that totaled \$15.4 million, which included \$2.3 million of net proceeds received in March 2017 from sales of common stock under our at-the-market (“ATM”) program. Under the rules and regulations of the Australian Securities Exchange (the “ASX”), subsequent to March 31, 2017 we could sell up to approximately 3.7 million additional shares of common stock under the ATM program without the need to obtain stockholder approval. During the period between April 1, 2017 and May 4, 2017, a total of approximately 3.6 million shares of common stock were sold for approximately \$6.0 million of net proceeds. On May 4, 2017, we filed a preliminary proxy statement in connection with a special meeting of stockholders to be held on June 27, 2017 to seek stockholder ratification of the ATM sales in order to refresh the Company’s capacity to issue shares of common stock without prior stockholder approval pursuant to ASX Listing Rule 7.1.

With the exception of net income for the fiscal year ended June 30, 2015 resulting from the \$25.0 million ILUVIEN FDA-approval milestone, we have generally incurred operating losses since inception, and at March 31, 2017, we had a total accumulated deficit of \$304.6 million. We have financed our operations primarily from the proceeds of sales of our equity securities and receipt of license fees, milestone payments, research and development funding and royalty income from our collaboration partners. 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 Alimera’s 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 March 31, 2017, together with expected cash inflows under existing collaboration agreements and the issuance of the additional 3.7 million shares of common stock under the ATM program noted above, will enable us to fund our operations as currently planned through approximately the third quarter of fiscal 2018. This estimate excludes any potential receipts under the Alimera agreement. Our ability to fund planned operations beyond the third quarter of fiscal 2018 may require us to reduce or defer operating expenses and/or to obtain stockholder approval, as noted above, in order to further utilize our ATM program or to access additional financing through other sources. The timing and extent of our implementation of these plans is expected to depend on the amount and timing of cash receipts from Alimera’s commercialization of ILUVIEN, proceeds from any future collaboration or other agreements and/or proceeds from any financing transactions. There is no assurance that we will receive significant, if any, revenues from future sales of ILUVIEN or cash from any other sources.

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The additional capital we will require will be influenced by many factors, including, but not limited to:

- whether, when and to what extent we receive future revenues with respect to the commercialization of ILUVIEN;
- the timing and cost of development, regulatory approval and commercialization of Durasert three-year uveitis and the manner in which we commercialize the product;
- 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 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 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.

We do not know if additional capital will be available when needed or on terms favorable to us or our stockholders. Collaboration, licensing and other agreements may not be available on favorable terms, or at all. We do not know when or if we will receive any substantial funds from Alimera's commercialization of ILUVIEN. If we seek to sell shares under our ATM program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the ASX and the NASDAQ Global Market require us to obtain stockholder approval for sales of equity securities under certain circumstances, which could delay or prevent us from raising capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' 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 Durasert three-year uveitis or other new products, if any, and 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		Change
	March 31,		
	2017	2016	
Net loss:	<u>\$ (12,369)</u>	<u>\$ (15,160)</u>	<u>\$ 2,791</u>
Changes in current assets and liabilities	(451)	899	(1,350)
Other adjustments to reconcile net loss to cash flows from operating activities	(3,218)	2,292	(5,510)
Net cash used in operating activities	<u>\$ (16,038)</u>	<u>\$ (11,969)</u>	<u>\$ (4,069)</u>
Net cash provided by investing activities	<u>\$ 11,203</u>	<u>\$ 859</u>	<u>\$ 10,344</u>
Net cash provided by financing activities	<u>\$ 2,404</u>	<u>\$ 16,868</u>	<u>\$ (14,464)</u>

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For the nine months ended March 31, 2017, net cash used in operating activities increased by \$4.1 million compared to the nine months ended March 31, 2016, due entirely to higher operating cash outflows. Increased operating cash outflows consisted of approximately (i) \$2.0 million of personnel costs, primarily severance compensation paid to our former CEO, Vice President, Corporate Affairs and General Counsel and U.K. employees, payment of higher incentive compensation awards, and the previously announced current year additions to our executive management team; (ii) \$1.9 million of professional fees for uveitis market assessment and commercialization strategies, our CEO transition and elimination of the position of Vice President, Corporate Affairs and General, arbitration proceedings with Alimera, regulatory and clinical consulting services associated with our Durasert three-year uveitis Phase 3 clinical development program and planned MAA and NDA filings, our U.K. restructuring and higher patent legal fees; and (iii) \$225,000 of CRO payments associated with Durasert three-year uveitis clinical development, primarily due to the timing and amounts of contractual milestone payments.

Net cash provided by investing activities consisted predominantly of \$11.2 million of maturities of marketable securities, net of purchases, during the nine months ended March 31, 2017 compared to \$926,000 of maturities of marketable securities, net of purchases, during the nine months ended March 31, 2016.

Net cash provided by financing activities for the nine months ended March 31, 2017 consisted of \$2.3 million of proceeds, net of share issue costs, from the March 2017 sale of 1,411,686 common shares under our ATM facility and \$99,000 of proceeds from the exercise of stock options. 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.

We had no borrowings or line of credit facilities as of March 31, 2017.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of March 31, 2017 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 have historically conducted 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, which have been significantly reduced in connection with the U.K. restructuring announced in July 2016. 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, 2017 compared to the prior year's quarter resulted in a net decrease in research and development expenses of \$24,000. 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, 2017 would have decreased or increased by approximately \$7,500, respectively. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of comprehensive loss exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the Pound Sterling to the U.S. dollar also impacted total stockholders' equity. As reported in the consolidated statement of comprehensive loss, the relative strengthening of the U.S. dollar in relation to the Pound Sterling at March 31, 2017 compared to June 30, 2016 resulted in \$30,000 of other comprehensive loss for the nine months ended March 31, 2017 due to the translation of £192,000 of net assets of our U.K. operations into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at March 31, 2017 in relation to the Pound Sterling, our stockholders' equity at March 31, 2017 would have decreased or increased, respectively, by \$12,000.

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, 2017. The term "disclosure

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controls and procedures”, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2017, 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 quarter ended March 31, 2017, 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, 2016 filed with the Securities and Exchange Commission (the “SEC”) on September 13, 2016.

Item 6. Exhibits

- 10.1+ Retention Bonus Letter, dated January 5, 2017, by and between pSivida Corp. and Leonard Ross (incorporated herein by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed on January 10, 2017)
- 10.2 At Market Issuance Sales Agreement, dated February 8, 2017, by and between pSivida Corp. and FBR Capital Markets & Co. (incorporated herein by reference to Exhibit 10.1 to the Registrant’s Current Report on Form 8-K filed on February 8, 2017)
- 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, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Comprehensive Loss; (iii) Condensed Consolidated Statement of Stockholders’ Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements

+ Indicates management contract or compensatory plan

SIG NATURES

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 8, 2017

By: /s/ Nancy Lurker
Name: Nancy Lurker
Title: President and Chief Executive Officer

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Exhibit Index

No.	Description
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+ Indicates management contract or compensatory plan

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, Nancy Lurker, 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 8, 2017

/s/ Nancy Lurker

Name: Nancy Lurker

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 8, 2017

/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, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nancy Lurker, 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 8, 2017

/s/ Nancy Lurker

Name: Nancy Lurker
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, 2017, 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 8, 2017

/s/ Leonard S. Ross

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