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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 September 30, 2014

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER 000-51122

pSivida Corp.
(Exact name of registrant as specified in its charter)

Delaware	**26-2774444**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
480 Pleasant Street Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

There were 29,347,595 shares of the registrant’s common stock, $0.001 par value, outstanding as of November 5, 2014.

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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)

	September 30, 2014	June 30, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 11,384	$ 15,334
Marketable securities	2,924	2,944
Accounts and other receivables	25,462	517
Prepaid expenses and other current assets	915	547
Total current assets	40,685	19,342
Property and equipment, net	261	297
Intangible assets, net	2,528	2,765
Other assets	116	117
Restricted cash	150	150
Total assets	$ 43,740	$ 22,671
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,105	$ 464
Accrued expenses	1,103	1,524
Deferred revenue	104	138
Total current liabilities	2,312	2,126
Deferred revenue, less current portion	5,584	5,584
Deferred rent	42	37
Total liabilities	7,938	7,747
Stockholders' equity:		
Preferred stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $.001 par value, 60,000,000 shares authorized, 29,337,595 and 29,298,558 shares issued and outstanding at September 30, 2014 and June 30, 2014, respectively	29	29
Additional paid-in capital	291,229	290,864
Accumulated deficit	(256,447)	(277,013)
Accumulated other comprehensive income	991	1,044
Total stockholders' equity	35,802	14,924
Total liabilities and stockholders' equity	$ 43,740	$ 22,671

See notes to condensed consolidated financial statements

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

	Three Months Ended September 30,	
	2014	2013
Revenues:		
Collaborative research and development	$25,081	$ 173
Royalty income	226	424
Total revenues	25,307	597
Operating expenses:		
Research and development	2,784	2,504
General and administrative	1,734	1,811
Total operating expenses	4,518	4,315
Income (loss) from operations	20,789	(3,718)
Interest income	3	1
Income (loss) before income taxes	20,792	(3,717)
Income tax (expense) benefit	(226)	30
Net income (loss)	$20,566	$ (3,687)
Net income (loss) per common share:		
Basic	$ 0.70	$ (0.14)
Diluted	$ 0.67	$ (0.14)
Weighted average common shares:		
Basic	29,323	25,918
Diluted	30,765	25,918
Net income (loss)	$20,566	$ (3,687)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	(50)	65
Net unrealized loss on marketable securities	(3)	—
Other comprehensive (loss) income	(53)	65
Comprehensive income (loss)	$20,513	$ (3,622)

See notes to condensed consolidated financial statements

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at July 1, 2014	29,298,558	$ 29	$290,864	$ (277,013)	$ 1,044	$ 14,924
Net income	—	—	—	20,566	—	20,566
Other comprehensive loss	—	—	—	—	(53)	(53)
Exercise of stock option	39,037	—	56	—	—	56
Stock-based compensation	—	—	309	—	—	309
Balance at September 30, 2014	29,337,595	$ 29	$291,229	$ (256,447)	$ 991	$ 35,802

See notes to condensed consolidated financial statements

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

	Three Months Ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net income (loss)	$ 20,566	$ (3,687)
Adjustments to reconcile net income (loss) to cash flows from operating activities:		
Amortization of intangible assets	196	192
Depreciation of property and equipment	35	39
Stock-based compensation expense	309	217
Amortization of bond premium on marketable securities	18	17
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(25,323)	(457)
Accounts payable and accrued expenses	235	(438)
Deferred revenue	(35)	340
Deferred rent	5	—
Net cash used in operating activities	(3,994)	(3,777)
Cash flows from investing activities:		
Purchases of marketable securities	(251)	—
Maturities of marketable securities	250	1,450
Purchases of property and equipment	(6)	(8)
Net cash (used in) provided by investing activities	(7)	1,442
Cash flows from financing activities:		
Proceeds from issuance of stock, net of issuance costs	—	9,981
Proceeds from exercise of stock options	56	—
Net cash provided by financing activities	56	9,981
Effect of foreign exchange rate changes on cash and cash equivalents	(5)	1
Net (decrease) increase in cash and cash equivalents	(3,950)	7,647
Cash and cash equivalents at beginning of period	15,334	6,899
Cash and cash equivalents at end of period	$ 11,384	$14,546

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 September 30, 2014 and for the three months ended September 30, 2014 and 2013 are unaudited. Certain information in the footnote disclosures of these financial statements has been condensed or omitted in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC"). These financial statements should be read in conjunction with the Company's audited consolidated financial statements and footnotes included in its Annual Report on Form 10-K for the fiscal year ended June 30, 2014. In the opinion of management, these statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended June 30, 2014, and include all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair presentation of the Company's financial position, results of operations, comprehensive income (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 months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the entire fiscal year or any future period.

The Company develops tiny, sustained-release products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Using its core technology platforms, Durasert™ and Tethadur™, the Company is focused on treatment of chronic diseases of the back of the eye and is also exploring applications outside ophthalmology. The Company's lead product candidate Medidur™ is in a pivotal Phase III clinical trial, its lead licensed product ILUVIEN® was recently approved by the U.S. Food and Drug Administration ("FDA") in the U.S. and was previously approved in the European Union ("EU"), and the Company's pipeline includes potential product candidates at earlier stages of development. The Company's Durasert technology is the basis of three of the four sustained-release products for treatment of retinal diseases currently approved in the U.S. or EU. The Company's strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

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

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

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

ILUVIEN is commercially available in the United Kingdom ("U.K.") and Germany for the treatment of chronic DME considered insufficiently responsive to available therapies and has been approved or is pending authorization in fifteen other EU countries.

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

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

The Company has a history of operating losses and has financed its operations primarily from the proceeds of sales of its equity securities and the receipt of license fees, research and development funding and royalty income from its collaboration partners. The Company believes that its cash, cash equivalents and marketable securities of $14.3 million at September 30, 2014, together with the $25.0 million milestone payment subsequently received, will enable the Company to maintain its current and planned operations into calendar year 2017. This estimate excludes any potential net profits receipts from sales of ILUVIEN.

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

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

2. License and Collaboration Agreements

Alimera

Under the collaboration agreement with Alimera, as amended in March 2008 (the "Alimera Agreement"), the Company licensed to Alimera the rights to develop, market and sell certain product candidates, including ILUVIEN, and Alimera assumed all financial responsibility for the development of licensed products. In October 2014, the Company received a $25.0 million milestone payment from Alimera as a result of the FDA approval of ILUVIEN. In addition, the Company is entitled to receive 20% of any net profits (as defined) on sales of each licensed product (including ILUVIEN) by Alimera, measured on a quarter-by-quarter and country-by-country basis. Alimera may recover 20% of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country, but only by an offset of up to 4% of the net profits earned in that country each quarter, reducing the Company's net profit share to 16% in each country until those net losses are recouped. In the event that Alimera sublicenses commercialization in any country, the Company is entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions.

The Company's performance obligations ended on December 31, 2009 and, accordingly, all amounts received thereafter under the Alimera Agreement are recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amounts are both fixed and determinable and reasonably assured of collectability. Alimera received a $25.0 million loan advance on September 30, 2014 to fund the FDA approval milestone and, on that basis, collectability was deemed to be reasonably assured at that date and the amount was recorded as collaborative research and development revenue in the current period.

Revenue related to the Alimera Agreement totaled $25.0 million and $13,000 for the three months ended September 30, 2014 and 2013, respectively, and, in addition to the FDA milestone, consisted of patent fee reimbursements.

Pfizer

In June 2011, the Company and Pfizer entered into an Amended and Restated Collaborative Research and License Agreement (the "Restated Pfizer Agreement") to focus solely on the development of a sustained-release bioerodible micro-insert designed to deliver latanoprost for human ophthalmic disease or conditions other than

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

As a result of the material modification of the Pfizer arrangement, the estimated selling price of the combined deliverables under the Restated Pfizer Agreement of $6.7 million is being recognized as collaborative research and development revenue over the expected performance period using the proportional performance method. The Company recorded no revenue and $31,000 for the three months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, the Company continues to evaluate the Latanoprost Product and, consequently, the Company cannot currently estimate the remaining performance period. As a result, total deferred revenue of approximately $5.6 million at each of September 30, 2014 and June 30, 2014 was classified as noncurrent. Costs associated with developing the Latanoprost Product are reflected in operating expenses in the period in which they are incurred.

Pfizer owned approximately 6.3% of the Company’s outstanding common stock at September 30, 2014.

Bausch & Lomb

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

Royalty income totaled $226,000 and $424,000 for the three months ended September 30, 2014 and 2013, respectively. Accounts receivable from Bausch & Lomb totaled $235,000 at September 30, 2014 and $302,000 at June 30, 2014.

Enigma Therapeutics

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with Enigma Therapeutics Limited (“Enigma”) for the development of BrachySil, the Company’s BioSilicon product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of $100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. Enigma is obligated to pay an annual license maintenance fee of $100,000 by the end of each calendar year, the first of which was received in January 2014. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any patent maintenance costs, sales-based royalties and sublicensee sales-based royalties earned to the extent such amounts, in the aggregate, exceed the $100,000 annual license maintenance fee. The Company has no consequential performance obligations under the Enigma license agreement and, accordingly, any amounts to which the Company is entitled under the agreement are recognized as revenue on the earlier of receipt or when collectability is reasonably assured. There was no revenue related to the Enigma agreement for each of the three months ended September 30, 2014 and 2013. As of September 30, 2014, no deferred revenue was recorded for this agreement.

Evaluation Agreements

The Company from time to time enters into funded agreements to evaluate the potential use of its technology systems for sustained release of third party drug candidates in the treatment of various diseases. Consideration received is generally recognized as revenue over the term of the feasibility study agreement. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the evaluation agreement. Revenues under evaluation agreements totaled $35,000 and $173,000 for the three months ended September 30, 2014 and 2013, respectively.

3. Intangible Assets

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

	Three Months Ended September 30, 2014	Year Ended June 30, 2014
Patented technologies		
Gross carrying amount at beginning of period	$ 41,689	$ 38,941
Foreign currency translation adjustments	(1,191)	2,748
Gross carrying amount at end of period	40,498	41,689
Accumulated amortization at beginning of period	(38,924)	(35,511)
Amortization expense	(196)	(778)
Foreign currency translation adjustments	1,150	(2,635)
Accumulated amortization at end of period	(37,970)	(38,924)
Net book value at end of period	$ 2,528	$ 2,765

The Company amortizes its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization of intangible assets totaled $196,000 and $192,000 for the three months ended September 30, 2014 and 2013, respectively. The carrying value of intangible assets at September 30, 2014 of $2.5 million (approximately $1.7 million attributable to the Durasert technology and $0.8 million attributable to the BioSilicon™ technology (including Tethadur)) is expected to be amortized on a straight-line basis over the remaining estimated useful life of 3.25 years, or approximately $778,000 per year.

4. Marketable Securities

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

	September 30, 2014		
	Amortized Cost	Unrealized Loss	Fair Value
Corporate bonds	$ 2,678	$ (4)	$ 2,674
Commercial paper	250	—	250
Total marketable securities	$ 2,928	$ (4)	$ 2,924

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

During the three months ended September 30, 2014, $251,000 of marketable securities were purchased and $250,000 of such securities matured. At September 30, 2014, the marketable securities had maturities ranging from 3.5 to 8 months, with a weighted average maturity of 5 months.

5. Fair Value Measurements

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

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

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

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

	September 30, 2014			
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 10,800	$ 10,800	$ —	$ —
Marketable securities				
Corporate bonds	2,674	2,172	502	—
Commercial paper	250	—	250	—
	$ 13,724	$ 12,972	$ 752	$ —

	June 30, 2014			
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	$ 14,260	$ 14,260	$ —	$ —
Marketable securities				
Corporate bonds	2,444	1,936	508	—
Commercial paper	500	—	500	—
	$ 17,204	$ 16,196	$ 1,008	$ —

6. Accrued Expenses

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

	September 30, 2014	June 30, 2014
Personnel costs	$ 332	$ 952
Professional fees	260	249
Clinical	211	316
Income taxes	260	—
Other	40	7
	$ 1,103	$ 1,524

7. Stockholders' Equity

In December 2013, the Company entered into an at-the-market ("ATM") program pursuant to which the Company may, at its option, offer and sell shares of its common stock from time to time for an aggregate offering price of up to $19.2 million, representing the then remaining balance of the Company's shelf registration statement. In connection with execution of the ATM program, the Company incurred transaction costs of $153,000. In addition, the Company pays the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. During the three months ended September 30, 2014, the Company did not sell any shares under this program.

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

Warrants to Purchase Common Shares

During each of the three month periods ended September 30, 2014 and 2013, there were a total of 1,176,105 outstanding and exercisable warrants to purchase common shares at a weighted-average exercise price of $3.67. At September 30, 2014, the remaining term of these warrants ranged from 1.3 to 2.9 years, representing a weighted average period of 2.1 years.

Incentive Plan

The Company's 2008 Incentive Plan (the "2008 Plan") provides for the issuance of stock options and other stock awards to directors, employees and consultants. At September 30, 2014, a total of 6,341,255 shares of common stock were authorized for issuance under the 2008 Plan, of which 1,440,497 were available for grant of future awards. Shares issuable under the 2008 Plan are subject to an annual increase pursuant to the terms of the plan. The following table provides a reconciliation of stock option activity under the 2008 Plan for the three months ended September 30, 2014:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at July 1, 2014	3,791,001	$ 3.08		
Granted	456,200	4.47		
Exercised	(39,037)	1.43		
Forfeited	(2,125)	5.05		
Outstanding at September 30, 2014	4,206,039	$ 3.24	6.63	$ 5,268
Outstanding at September 30, 2014 - vested or unvested and expected to vest	4,117,608	$ 3.23	6.58	$ 5,217
Exercisable at September 30, 2014	2,960,677	$ 3.02	5.73	$ 4,396

During the three months ended September 30, 2014, the Company granted 456,200 options to employees with ratable annual vesting over 4 years and a 10-year term. The weighted-average grant date fair value of these option grants was $3.44 per share. A total of 534,158 options vested during the three months ended September 30, 2014. In determining the grant date fair value of options, the Company uses the Black-Scholes option pricing model. The Company calculated the Black-Scholes value of options awarded during the three months ended September 30, 2014 based on the following key assumptions:

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

Stock-Based Compensation Expense

The Company's statements of comprehensive income (loss) included total compensation expense from stock-based payment awards for the three months ended September 30, 2014 and 2013, as follows (in thousands):

	Three Months Ended September 30,	
	2014	2013
Compensation expense included in:		
Research and development	$ 112	$ 77
General and administrative	197	140
	$ 309	$ 217

At September 30, 2014, there was approximately $2.1 million of unrecognized compensation expense related to unvested options under the 2008 Plan, which is expected to be recognized as expense over a weighted average period of approximately 2.0 years.

8. Income Taxes

The Company recognizes deferred tax assets and liabilities for estimated future tax consequences of events that have been recognized in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax assets will not be realized. Because of its historical losses from operations, the Company established a valuation allowance for the net deferred tax assets. The Company

recorded an income tax expense of $226,000 for the three months ended September 30, 2014 and an income tax benefit of $30,000 for the three months ended September 30, 2013. The current period income tax expense predominantly reflects a $260,000 federal alternative minimum tax liability based upon projected taxable income for the tax year ending December 31, 2014, which is primarily attributable to revenue recognition of the $25.0 million FDA approval milestone. Earned foreign research and development tax credits totaled $34,000 and $30,000 for the three months ended September 30, 2014 and 2013, respectively.

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

9. Commitments and Contingencies

In March 2014, the Company leased new U.S. office and laboratory space in Watertown, Massachusetts and provided a cash-collateralized $150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease. The initial lease term extends through April 2019, with a five-year renewal option at market rates. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts.

At September 30, 2014, the Company was subject to various routine legal proceedings and claims incidental to its business, which management believes will not have a material effect on the Company's financial position, results of operations or cash flows.

10. Net Income (Loss) per Share

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

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

	Three Months Ended September 30,	
	2014	2013
Number of common shares - basic	29,322,708	25,917,924
Effect of dilutive securities:		
Stock options	1,164,260	—
Warrants	277,926	—
Number of common shares - diluted	30,764,894	25,917,924

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

	September 30,	
	2014	2013
Options outstanding	1,230,724	3,959,699
Warrants outstanding	552,500	1,176,105
	1,783,224	5,135,804

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Note Regarding Forward-Looking Statements

Various statements made in this Quarterly Report on Form 10-Q are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. All statements other than statements of current or historical facts are forward-looking statements, including, without limitation, any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as "likely", "expect", "intend", "anticipate", "believe", "estimate", "plan", "project", "forecast" and "outlook".

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: uncertainties with respect to: ability to achieve profitable operations and access to capital; fluctuations in operating results; further impairment of intangible assets; decline in Retisert royalties; successful commercialization of, and receipt of revenues from, ILUVIEN for DME; effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; consequences of fluocinolone acetonide side effects; number of clinical trials necessary to support an NDA for, and regulatory approval and successful commercialization, of Medidur; development of the Latanoprost Product and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver large biologic molecules and development of products using Tethadur; ability to successfully develop product candidates, complete clinical trials and receive regulatory approvals; ability to market and sell products; success of current and future license agreements; termination of license agreements; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the SEC. You should read and interpret any forward-looking statements together with these risks. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the date on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

Our Business

We develop tiny, sustained-release products designed to deliver drugs and biologics at a controlled and steady rate for weeks, months or years. Using our core technology platforms, Durasert™ and Tethadur™, we are focused on treatment of chronic diseases of the back of the eye and are also exploring applications outside ophthalmology. Our lead product candidate Medidur™ is in a pivotal Phase III clinical trial, our lead licensed product ILUVIEN® was recently approved by the U.S. Food and Drug Administration ("FDA") in the U.S. and was previously approved in the European Union ("EU"), and our pipeline includes potential product candidates at earlier stages of development. Our Durasert technology is the basis of three of the four sustained-release products for treatment of retinal diseases that have been approved in the U.S. or EU. Our strategy includes developing products independently while continuing to leverage our technology platforms through collaborations and license agreements.

Medidur, our lead development product, is an injectable, sustained-release micro-insert designed to provide treatment of posterior uveitis over a period of up to three years. Medidur uses the same Durasert micro-insert used in ILUVIEN (same design, same drug, same polymers, same release rate) and delivers a lower dose of the same drug as our FDA-approved Retisert® for posterior uveitis, which is licensed to Bausch & Lomb. We expect to seek FDA approval based on safety and efficacy data from our single ongoing Phase III trial, with supplemental clinical data

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

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

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

ILUVIEN is commercially available in the United Kingdom ("U.K.") and Germany for the treatment of chronic DME considered insufficiently responsive to available therapies and has been approved or is pending authorization in fifteen other EU countries.

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

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

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

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

Critical Accounting Policies and Estimates

The preparation of consolidated financial statements in conformity with GAAP requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates, judgments and assumptions on historical experience, anticipated results and trends, and on various other factors that we believe are reasonable under the circumstances at the time. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty. Actual results may differ from our estimates under different assumptions or conditions. In our Annual Report on Form 10-K for the year ended June 30, 2014 ("fiscal year 2014"), we set forth our critical accounting policies and estimates, which included revenue recognition, recognition of expense in outsourced clinical trial agreements and valuation of intangible assets. There have been no material changes to our critical accounting policies from the information provided in our Annual Report on Form 10-K for fiscal year 2014.

Results of Operations

Three Months Ended September 30, 2014 Compared to Three Months Ended September 30, 2013:

	Three Months Ended September 30,		Change	
	2014	2013	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	$25,081	$ 173	$24,908	**
Royalty income	226	424	(198)	(47)%
Total revenues	25,307	597	24,710	**
Operating expenses:				
Research and development	2,784	2,504	280	11%
General and administrative	1,734	1,811	(77)	(4)%
Total operating expenses	4,518	4,315	203	5%
Income (loss) from operations	20,789	(3,718)	24,507	**
Interest income	3	1	2	200%
Income (loss) before income taxes	20,792	(3,717)	24,509	**
Income tax (expense) benefit	(226)	30	(256)	**
Net income (loss)	$20,566	$(3,687)	$24,253	**

** percentages not meaningful due to the effect of the $25.0 million non-recurring revenue in the current quarter

Revenues

Collaborative research and development revenues totaled $25.1 million for the three months ended September 30, 2014 compared to $173,000 for the three months ended September 30, 2013. This increase was primarily attributable to recognition of the $25.0 million FDA approval milestone earned from Alimera.

Royalty income decreased by $198,000, or 47%, to $226,000 for the three months ended September 30, 2014 compared to $424,000 for the three months ended September 30, 2013. We believe the lower Retisert sales causing this decrease were at least partly attributable to competition from new products, which may continue and result in lower fiscal 2015 royalty income compared to the prior year.

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

Research and Development

Research and development increased by $280,000, or 11%, to $2.8 million for the three months ended September 30, 2014 from $2.5 million for the same quarter a year earlier, primarily reflecting increased CRO costs for the clinical development of Medidur for posterior uveitis, as well as pre-clinical study costs associated with Tethadur. We expect to continue to incur significant research and development expense for Medidur during the remainder of fiscal year 2015 and in future periods until completion of Medidur clinical development.

General and Administrative

General and administrative decreased by $77,000, or 4%, to $1.7 million for the three months ended September 30, 2014 from $1.8 million for the same period in the prior year, primarily attributable to lower professional fees.

Income Tax (Expense) Benefit

Income tax expense of $226,000 for the three months ended September 30, 2014 was predominantly due to accrual of a $260,000 federal alternative minimum tax liability based upon projected taxable income for the tax year ending December 31, 2014. In addition, refundable foreign research and development tax credits totaled $34,000 and $30,000 for the three months ended September 30, 2014 and 2013, respectively.

Liquidity and Capital Resources

During the years ended June 30, 2014 and 2013, we financed our operations primarily from sales of equity securities and, to a lesser extent, from operating cash flows from license fees, research and development funding and royalty income from our collaboration partners. At September 30, 2014, our principal sources of liquidity were cash, cash equivalents and marketable securities that totaled $14.3 million, which was enhanced in October 2014 by the receipt of the $25.0 million milestone payment.

We have a history of operating losses, and at September 30, 2014, we had a total accumulated deficit of $256.4 million. We do not currently have any assured sources of future revenue and, other than for the quarter ending December 31, 2014, we expect negative cash flows from operations in subsequent quarters until we receive sufficient revenues from commercialization of ILUVIEN or one or more of our other product candidates achieve regulatory approval and provide us sufficient revenues. We believe that our capital resources at September 30, 2014, together with the milestone payment received in October 2014, will enable us to fund our current and planned operations into calendar year 2017. This estimate excludes any potential receipts of net profits under our Alimera collaboration agreement. Our ability to fund our planned operations beyond then is expected to depend on cash receipts from ILUVIEN or other products and from any future collaboration or other agreements and/or any financing transactions. There is no assurance that we will receive significant, if any, revenues from sales of ILUVIEN or cash from any other sources.

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

- whether, when and to what extent we receive revenues with respect to commercialization of ILUVIEN;
- the timing and cost of development, approval and marketing of Medidur for posterior uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- whether and when we initiate Phase II clinical trials for the Latanoprost Product and whether and when Pfizer exercises its option;
- whether and when we are able to enter into strategic arrangements for our product candidates and the nature of those arrangements;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital; and
- our views on the availability, timing and desirability of raising capital.

If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. Our existing ATM facility permits us to sell shares of common stock with an aggregate offering price of up to $10.7 million at September 30, 2014, but we do not know whether and to what extent we will seek to sell shares pursuant to that program and, if we are able to do so, on what terms. The state of the economy and the financial and credit markets at the time or times we seek additional financing may make it more difficult and more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products.

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

	Three Months Ended September 30,		
	2014	2013	Change
Net income (loss):	$ 20,566	$(3,687)	$ 24,253
Changes in operating assets and liabilities	(25,118)	(555)	(24,563)
Other adjustments to reconcile net income (loss) to cash flows from operating activities	558	465	93
Net cash used in operating activities	$ (3,994)	$(3,777)	$ (217)
Net cash (used in) provided by investing activities	$ (7)	$ 1,442	$ (1,449)
Net cash provided by financing activities	$ 56	$ 9,981	$ (9,925)

Net cash used in operating activities increased by $217,000 on a comparative basis, approximately evenly divided between an increase in operating cash outflows and a decrease of collaborative research and development and royalty operating cash inflows. Higher operating cash outflows consisted primarily of an approximate $700,000 increase of CRO payments associated with Medidur clinical development, partially offset by an approximate $370,000 decrease in incentive compensation awards and lower professional fees.

Net cash provided by investing activities for the three months ended September 30, 2013 resulted from approximately $1.5 million of maturities of marketable securities.

Net cash provided by financing activities for the three months ended September 30, 2014 consisted of $56,000 of proceeds from the exercise of stock options. This compared to $10.0 million of aggregate net proceeds in the prior year quarter from a July 2013 underwritten public offering of common shares.

We had no borrowings or line of credit facilities as of September 30, 2014.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2014 that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that would be material to investors.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Foreign Currency Exchange Rates

We conduct operations in two principal currencies, the U.S. dollar and the Pound Sterling (£). The U.S. dollar is the functional currency for our U.S. operations, and the Pound Sterling is the functional currency for our U.K. operations. Changes in the foreign exchange rate of the U.S. dollar and Pound Sterling impact the net operating expenses of our U.K. operations. The weakening of the U.S. dollar during the three months ended September 30, 2014 compared to the prior year's quarter resulted in a net increase in research and development expenses of $31,000. 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 September 30, 2014 would have decreased or increased by $21,000, respectively. All cash and cash equivalents, and most other asset and liability balances, are denominated in each entity's functional currency and, accordingly, we do not consider our statement of comprehensive income (loss) exposure to realized and unrealized foreign currency gains and losses to be significant.

Changes in the foreign exchange rate of the Pound Sterling to the U.S. dollar also impacted total stockholders' equity. As reported in the statement of comprehensive income (loss), the relative strengthening of the U.S. dollar in relation to the Pound Sterling at September 30, 2014 compared to June 30, 2014 resulted in $50,000 of other comprehensive loss for the three months ended September 30, 2014 due to the translation of £610,000 of net assets of our U.K. operations, predominantly the BioSilicon (including Tethadur) technology intangible asset, into U.S. dollars. For every incremental 5% strengthening or weakening of the U.S. dollar at September 30, 2014 in relation to the Pound Sterling, our stockholders' equity at September 30, 2014 would have decreased or increased, respectively, by $49,000.

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 September 30, 2014. The term "disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II: OTHER INFORMATION

Item 1A. Risk Factors

The following description of risk factors includes any material changes to, and supersedes, 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, 2014 filed with the Securities and Exchange Commission (the "SEC") on September 11, 2014.

ITEM 1A. RISK FACTORS

RISKS RELATED TO OUR COMPANY AND OUR BUSINESS

We do not know if or when we will achieve profitable operations from product sales, royalties and net profits participations and we may need additional capital to fund our operations, which may not be available on favorable terms or at all.

We have a history of operating losses, and at September 30, 2014, we had a total accumulated deficit of $256.4 million. During the past three fiscal years, we financed our operations primarily from sales of equity, as well as license fees, research and development funding and royalty income from our collaboration partners. We do not currently have any assured sources of revenue and, other than for the quarter ending December 31, 2014, we expect negative cash flows from operations in subsequent quarters until we receive sufficient revenues from commercialization of ILUVIEN or one or more of our other product candidates achieve regulatory approval and provide us sufficient revenues. We believe that our capital resources of $14.3 million at September 30, 2014, together with the $25.0 million milestone payment received in October 2014, should enable us to fund our operations as currently planned into calendar year 2017. This estimate excludes any potential net profits receipts from sales of ILUVIEN. We expect our ability to fund our planned operations beyond then will depend on the amount and timing of those payments, as well as proceeds from any future collaboration or other agreements and/or financing transactions.

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

- whether, when and to what extent we receive revenues with respect to the commercialization of ILUVIEN;

- the timing and cost of development, approval and marketing of Medidur for posterior uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- whether and when we initiate Phase II clinical trials for the Latanoprost Product and whether and when Pfizer exercises its option;
- whether and when we enter into strategic arrangements for our product candidates and the nature of those arrangements;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital; and
- our views on the availability, timing and desirability of raising capital.

If we determine that it is desirable or necessary to raise additional capital in the future, we do not know if it will be available when needed or on terms favorable to us or our stockholders. Our existing ATM facility permits us to sell shares of common stock with an aggregate offering price of up to $10.7 million at September 30, 2014, but we do not know whether and to what extent we will seek to sell shares pursuant to that program and, if we are able to do so, on what terms. The state of the economy and the financial and credit markets at the time or times we seek any additional financing may make it more difficult or more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and potential dilutive equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products.

If the recorded value of our intangible assets under GAAP is further impaired, our financial results could be materially adversely affected.

At September 30, 2014, we had $2.5 million of intangible assets relating to our Durasert and BioSilicon (including Tethadur) technologies on our balance sheet following impairment charges of $14.8 million as of December 31, 2011. We conduct impairment analyses of our intangible assets as required under GAAP and could take additional impairment charges in the future if the recorded values for our intangible assets were to exceed our assessment of the recoverability of the fair market value of those assets. Adverse events relating to the clinical development, regulatory approval and success of commercialization of products using those technologies and significant changes in our market capitalization could result in impairment charges. Further impairment charges on our intangible assets could have a material adverse effect on our results of operations in the quarter of the impairment.

Our operating results may fluctuate significantly from period to period.

Our operating results have fluctuated significantly from period to period in the past and may continue to do so in the future due to many factors, including:

- developments with respect to our products and product candidates, including pre-clinical and clinical trial results, regulatory developments and marketing and sales results;
- timing, receipt and amount of revenues, including receipt and recognition of collaborative research and development, milestone, royalty, net profit and other payments;
- announcement, execution, amendment and termination of collaboration agreements;
- scope, duration and success of collaboration agreements;
- costs of internally funded research and development costs, including pre-clinical studies and clinical trials;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- changes in accounting estimates, policies or principles and intangible asset impairments.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors in the financial community, which may result in decreases in our stock price.

There is no assurance our Retisert royalty income will continue at current levels or at all.

Retisert royalty income has declined significantly. We do not expect that it will grow materially, if at all, and it may continue to decline. There is no assurance that Bausch & Lomb will continue to market Retisert, which received marketing approval in 2005, and accordingly that we will continue to receive royalties from the sale of Retisert. Bausch & Lomb no longer markets Vitrasert.

RISKS RELATED TO THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

There is no assurance that our licensee will be successful in commercializing ILUVIEN for DME or if or when we will receive revenues from its commercialization of ILUVIEN for DME or the extent of those revenues. If our licensee is unable to successfully commercialize ILUVIEN for DME, it would adversely affect our future results of operations and financial position.

Our future financial results depend heavily on Alimera's ability to successfully commercialize ILUVIEN for DME. We do not know if, when, or to what extent we will receive revenues from the commercialization of ILUVIEN for DME. We are entitled to a net profit participation on a country-by-country and quarter-by-quarter basis on sales of ILUVIEN where Alimera markets ILUVIEN directly, such as the EU and U.S., and to a percentage of royalties and non-royalty consideration where Alimera sublicenses the marketing of ILUVIEN, such as Australia and New Zealand. The amount and timing of any revenues we receive will be affected, among other things, by the manner in which Alimera markets ILUVIEN, the amounts and timing of sales of ILUVIEN, commercialization costs incurred by Alimera's direct marketing efforts, and the terms of sublicense agreements.

The commercialization of ILUVIEN is a significant undertaking by Alimera, and ILUVIEN for DME is its first and only product. We do not know whether Alimera will be successful in financing, achieving additional marketing approvals for, obtaining adequate pricing and reimbursement for, successfully commercializing and achieving market acceptance of, and generating revenues to pSivida from, ILUVIEN for DME. Marketing in the U.S. and in additional countries in the EU will require expansion of Alimera's commercial infrastructure. Alimera's efforts to commercialize ILUVIEN successfully will be affected, among other things, by:

- Alimera's ability to recruit, manage and retain personnel, expand its sales, marketing and other infrastructure, and manage its growth;
- Alimera's ability to effectively market ILUVIEN, including accessing and persuading adequate numbers of ophthalmologists to prescribe ILUVIEN:
- the lack of other products to be offered by Alimera's sales personnel, which may put Alimera at a competitive disadvantage relative to companies with more extensive product lines;
- Alimera's ability to obtain regulatory approvals to market ILUVIEN and appropriate labeling, and to expand its marketing into countries where it has obtained approvals;
- Alimera's ability to obtain desirable pricing, insurance coverage and reimbursement for ILUVIEN;
- potential delays in the commercial launch in the U.S. or in one or more other countries;
- manufacturing or supply issues;
- risks related to operating in international jurisdictions; and
- Alimera's ability to generate adequate financial resources.

If Alimera is not successful in commercializing ILUVIEN for DME and generating payments to us, it would adversely affect our business, operating results and financial condition.

Sales of ILUVIEN for DME may be materially adversely affected by pricing and reimbursement decisions of regulatory bodies, insurers and others.

Prices, coverage and reimbursement to consumers of ILUVIEN for DME, like other drugs, are generally regulated by third-party payors, such as government health administration authorities and plans, private health insurers and other organizations and affect ILUVIEN's sales. The timing and complexity of those reimbursements also affect sales. Prices in the EU are generally lower and coverage and access to drugs more limited than in the U.S. For example, in the U.K. and Scotland, National Health Service coverage is limited to the treatment of the eyes of chronic DME patients unresponsive to existing therapies that have undergone cataract surgery, subject to simple patient access schemes. Alimera may not achieve satisfactory agreements with statutory or other insurers. In Germany, although ILUVIEN is sold without price restriction, physicians must submit individual funding requests for each patient. We do not know what levels of pricing will be approved or reimbursed for ILUVIEN, or what restrictions will be placed on its use or reuse in countries other than the U.K. and Germany. Alimera has delayed the launch of ILUVIEN in France until satisfactory agreement is reached on pricing with the French authorities. In the U.S., Alimera has said that it intends to offer extended payment terms to physicians in the launch year to accommodate expected time lags in the processing of reimbursement claims. Future sales of ILUVIEN and, accordingly, our net profits share may be adversely affected by pricing and reimbursement decisions, and such effects may be material.

The micro-insert for ILUVIEN and Medidur delivers FAc, a corticosteroid that has certain adverse side effects in the eye, which may affect the success of this micro-insert for treatment of DME and posterior uveitis.

The micro-insert for both ILUVIEN and Medidur delivers the non-proprietary corticosteroid fluocinolone acetonide (FAc), which is associated with cataract formation and elevated intraocular pressure and may increase the risk of glaucoma and related surgery to manage those side effects. Although Retisert, which delivers FAc to treat posterior uveitis, and ILUVIEN for DME have both been approved by the FDA, there is no assurance that Medidur will be safe and efficacious for the treatment of posterior uveitis in light of its expected side effects from FAc. These side effects may limit the population for which marketing authorization is granted or for which reimbursement is provided in one or more jurisdictions and/or adversely affect sales of Medidur, if approved, and/or ILUVIEN.

There is no assurance that we will be able to seek FDA approval of Medidur based on one Phase III trial together with a utilization study, and if we are required to conduct an additional Phase III trial, the time and expense required to obtain U.S. regulatory approval would increase.

If the results of our current Phase III Medidur trial are positive, we plan to seek FDA approval on the basis of this single Phase III trial together with additional clinical data from a planned open label study on use of our proprietary inserter. We plan to meet with the FDA to confirm this regulatory strategy. If we are required to complete two Phase III trials to seek FDA approval for Medidur, it would extend the time for filing an NDA and, accordingly, any regulatory approval of Medidur, and would also increase the cost of its development prior to approval.

There is no assurance that Medidur will be found to be safe and effective for the treatment of posterior uveitis.

We are optimistic that Medidur will be as efficacious for the treatment of posterior uveitis as Retisert, but with a better side effect profile than Retisert, comparable to ILUVIEN. However, this is only a hypothesis, and there is no assurance that the ongoing Phase III program for Medidur will demonstrate these results. While early interim data from the investigator-sponsored study of Medidur are consistent with this hypothesis, that trial is not complete, involves only up to 12 patients and is not intended to be a clinical trial that can serve as the basis for approval of Medidur. Data from the Retisert and ILUVIEN trials and early data from this investigator-sponsored study may not accurately predict the results of our Medidur Phase III program. There is no assurance that the Phase III program for Medidur will provide the necessary evidence of safety and efficacy required for approval by the FDA and other regulatory authorities. Actions by the FDA and other regulatory authorities with respect to Retisert and ILUVIEN are not predictive of the FDA's action with respect to Medidur.

There is no assurance that Pfizer will exercise its option with respect to the Latanoprost Product, in which case we will not receive any further financial consideration under the Restated Pfizer Agreement.

Development of the Latanoprost Product through at least Phase II clinical trials is at our option and expense. Pfizer has an option for an exclusive, worldwide license to develop and commercialize the Latanoprost Product upon our completion of Phase II clinical trials or upon our cessation of development of the Latanoprost Product at any time prior to completion of those trials. There is no assurance that we will commence or complete Phase II clinical trials for the Latanoprost Product; that, if completed, the trials will be successful; that Pfizer will, in any event, exercise its option; that, if exercised, Pfizer will commence Phase III clinical trials; or that the Latanoprost Product will achieve successful Phase III trial results, regulatory approvals or commercial success. As a result, there is no assurance that we will receive any further licensing, milestone or royalty payments under the Restated Pfizer Agreement.

We do not know if we will be able to deliver proteins (including antibodies) and peptides with our Tethadur technology or that we will be able to develop product candidates or approved products using this technology.

Although we are optimistic that our Tethadur technology platform can provide sustained delivery of proteins (including antibodies) and peptides, and our data from in vitro studies have shown that the long-term sustained release of antibodies such as Avastin is achievable using Tethadur, our research is at an early stage. There is no assurance that our subsequent research will sustain these results or that we will be able to develop product candidates or approved products using Tethadur to deliver proteins and peptides.

Product development is very uncertain. If we do not develop product candidates to enter clinical trials, if we or any licensees do not initiate or complete clinical trials for our product candidates or if our product candidates do not receive the necessary regulatory approvals, neither we nor any licensees will be able to commercialize those product candidates and generate revenues for us.

Other than Medidur for posterior uveitis, for which a pivotal Phase III trial is ongoing, all of our product development is at earlier stages. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or result in approved products. There is no assurance that any feasibility study agreements we have, or enter into, with third parties, or our own research and development programs will result in any new product candidates, or that we or any licensees will commence clinical trials for any new product candidates or continue clinical trials once commenced. If clinical trials conducted by or for us or any licensees for any product candidates do not provide the necessary evidence of safety and efficacy, those product candidates will not receive the necessary regulatory approvals, cannot be sold, and will not generate revenues for us. Initial or subsequent clinical trials may not be initiated by or for us or any licensees for product candidates or may be delayed, terminated or fail due to many factors, including the following:

- decisions not to pursue development of product candidates due to pre-clinical or clinical trial results;
- lack of sufficient funding;
- inability to attract clinical investigators for trials;
- inability to recruit patients in sufficient numbers or at the expected rate;
- decisions by licensees not to exercise options for products or not to pursue products licensed to them;
- adverse side effects;
- failure of trials to demonstrate a product candidate’s safety and efficacy;
- failure to meet FDA or other regulatory agency requirements for clinical trial design, or inadequate clinical trial design;
- inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product;
- failures by, changes in our (or our licensees’) relationship with, or other issues at, contract research organizations (CROs), third-party vendors and investigators responsible for pre-clinical testing and clinical trials;
- inability to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with clinical materials;
- failure to comply with current good laboratory practices (GLP), good clinical practices (GCP), good manufacturing practices (cGMP) or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of products;
- requests by regulatory authorities for additional data or clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differ from our (or our licensees’) interpretations or conclusions;
- governmental or regulatory delays, or changes in approval policies or regulations; and
- developments, clinical trial results and other factors with respect to competitive products and treatments.

Results from pre-clinical testing and early clinical trials often do not accurately predict results of later clinical trials. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Data from pre-clinical studies, early clinical trials and interim periods in multi-year trials are preliminary and may change, and final data from pivotal trials for such products may differ significantly. Adverse side effects may develop that delay, limit or prevent the regulatory approval of products, or cause such regulatory approvals to be limited or even rescinded. Additional trials necessary for approval may not be undertaken or may ultimately fail to establish the safety and efficacy of our product candidates.

The FDA or other relevant regulatory agencies may not approve our product candidates for manufacture and sale, and any approval by the FDA does not ensure approval by other regulatory agencies or vice versa (which could require us to comply with numerous and varying regulatory requirements, possibly including additional clinical testing). Any product approvals we or our licensees achieve could also be withdrawn for failure to comply with regulatory standards or due to unforeseen problems after the products' marketing approval. In either case, marketing efforts with respect to the affected product would have to cease. In addition, the FDA or other regulatory agencies may impose limitations on the indicated uses for which a product may be marketed. The imposition by the FDA or other relevant regulatory organizations of any such limitations on the indicated uses for which any of our products may be marketed would reduce the size of, or otherwise limit, the potential market for the product subject to such limitations.

In addition to testing, regulatory agencies impose various requirements on manufacturers and sellers of products under their jurisdiction, such as packaging, labeling, manufacturing practices, record keeping and reporting. Regulatory agencies may also require post-marketing testing and surveillance programs to monitor a product's effects. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals.

We do not currently have sales and marketing capacity, and there is no assurance that we will be able to develop the capacity to successfully market and sell any products we independently develop.

Our strategy includes independently developing products and marketing and selling them ourselves. Successfully commercializing products requires substantial efforts by experienced, skillful personnel as well as significant expenditure of funds. However, we currently have no marketing or sales staff and no experience in commercializing products. We may not be able to hire and manage a successful sales and marketing capability or have the resources necessary to fund the development of this capability for the independent commercialization of our products.

The success of our current and possible future collaborative and licensing arrangements depends and will depend heavily on the experience, resources, efforts and activities of our licensees, and if they are not successful in developing and marketing our products, it will adversely affect our revenues, if any, from those products.

Our business strategy includes continuing to leverage our technology platforms by entering into collaborative and licensing arrangements for the development and commercialization of our product candidates, where appropriate. The success of current and future collaborative and licensing arrangements do and will depend heavily on the experience, resources, skill, efforts and activities of our licensees. Our licensees have had, and are expected to have, significant discretion in making decisions related to the development of product candidates and the commercialization of products under these collaboration agreements. Risks that we face in connection with our collaboration and licensing strategy include the following:

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;
- we are required, and expect to be required, under our collaborative and licensing arrangements, not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees may change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

We currently have collaboration and licensing arrangements with various companies, most significantly Alimera and Bausch & Lomb. While Bausch & Lomb has significant experience in the ophthalmic field and substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to Retisert, and we do not expect revenues from Retisert to increase materially and they may decline further. Although we believe potential revenues from ILUVIEN for DME are important to our future results of operation and financial condition, Alimera has limited experience and limited financial resources, and ILUVIEN for DME is Alimera's first and only commercial product. If our current and future licensees are not successful in developing and marketing our products, it will adversely affect our revenues, if any, from those products.

Our current licensees may terminate their agreements with us at any time or fail to fulfill their obligations under those agreements, and, if they do, we will lose the benefits of those agreements.

Our licensees have rights of termination under our agreements with them and could terminate those agreements without cause on short notice. Further, our licensees may fail to fulfill their obligations under their agreements, or we may disagree with them over the rights and obligations under those agreements, which could result in breach of the agreements and/or termination. Exercise of termination rights by one or more of our licensees or by us may leave us without the financial benefits and development, marketing or sales resources provided under the terminated agreement. It could be necessary for us to replace, or seek to provide ourselves, the services provided by the licensee, and there is no assurance we would be successful in doing so. It could delay, impair or stop the development or commercialization of products or product candidates licensed to them or require significant additional capital investment by us, which we may not have the resources to fund. If any of our licensees do not perform their obligations under our agreements or if any of those agreements are terminated, it could have an adverse effect on our business, financial condition and results of operations

If competitive products receive regulatory approval or reach the market earlier, are more effective, have fewer side effects, are more effectively marketed or cost less than our products or product candidates, they may not be approved, may not achieve the sales we anticipate and could be rendered noncompetitive or obsolete.

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development, ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may more effectively treat our targeted diseases or their underlying causes, which could result in our product candidates not being approved, reduce demand for our products and product candidates or render them noncompetitive or obsolete.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. Our competitors may succeed in developing alternate technologies and products that, in comparison to the products we have and are seeking to develop:

- are more effective and easier to use;
- are more economical;
- have fewer side effects;
- offer other benefits; or
- may otherwise render our products less competitive or obsolete.

Many of these competitors have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances and manufacturing and marketing products than we do.

Our products and product candidates may not achieve and maintain market acceptance and may never generate significant revenues.

In both domestic and foreign markets, the commercial success of our products and product candidates will require not only obtaining regulatory approvals, but also obtaining market acceptance by retinal specialists and other doctors, patients, government health administration authorities and other third-party payors. Whether and to what extent our products and product candidates achieve and maintain market acceptance will depend on a number of factors, including demonstrated safety and efficacy, cost-effectiveness, potential advantages over other therapies, our and our collaborative partners' marketing and distribution efforts and the reimbursement policies of government

and other third-party payors. In particular, if government and other third-party payors do not recommend our products and product candidates, limit the indications for which they are recommended, or do not provide adequate and timely coverage and reimbursement levels for our products, the market acceptance of our products and product candidates will be limited. Both government and other third-party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they may challenge the price and cost-effectiveness of our products, or refuse to provide coverage for our products. If our products and product candidates fail to achieve and maintain market acceptance, they may fail to generate significant revenues and our business may be significantly harmed.

Guidelines, recommendations and studies published by various organizations could reduce the use of our products and potential use of product candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' products and product candidates. Any such guidelines, recommendations or studies that reflect negatively on our products or product candidates, either directly or relative to our competitive products, could result in current or potential decreased use, sales of, and revenues from one or more of our products and product candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our products and product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We rely heavily upon patents and trade secrets to protect our proprietary technologies. If we fail to protect our intellectual property or infringe on others' technologies, our ability to develop and market our products and product candidates may be compromised.

Our success is dependent on whether we can obtain patents, defend our existing patents and operate without infringing on the proprietary rights of third parties. As of October 31, 2014, we had 229 patents and 112 pending patent applications, including patents and pending applications covering our Durasert, Tethadur and other technologies. Intellectual property protection of our technologies is uncertain. We expect to seek to patent and protect our proprietary technologies. However, there is no assurance that any additional patents will be issued to us as a result of our pending or future patent applications or that any of our patents will withstand challenges by others. In addition, we may not have sufficient funds to patent and protect our proprietary technologies to the extent that we would desire, or at all. If we were determined to be infringing any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses, pay royalties or cease certain operations. We may not be able to obtain any required licenses on commercially favorable terms, if at all. In addition, many foreign country laws may treat the protection of proprietary rights differently from, and may not protect our proprietary rights to the same extent as, laws in the U.S. and Patent Co-operation Treaty countries.

Prior art may reduce the scope or protection of, or invalidate, our patents. Previously conducted research or published discoveries may prevent our patents from being granted, invalidate issued patents or narrow the scope of any protection obtained. Reduction in scope of protection or invalidation of our licensed or owned patents, or our inability to obtain patents, may enable other companies to develop products that compete with our products and product candidates on the basis of the same or similar technology. As a result, our patents and those of our licensors may not provide any, or sufficient, protection against competitors. While we have not been, and are not currently, involved in any litigation over intellectual property, such litigation may be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. We may also be sued by one or more third parties alleging that we infringe their intellectual property rights. Any intellectual property litigation would likely result in substantial costs to us and diversion of our efforts, and could prevent or delay our discovery or development of product candidates. If our competitors claim technology also claimed by us, and if they prepare and file patent applications in the U.S. or other jurisdictions, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or the appropriate foreign patent office to determine priority of invention, which could result in substantial cost to us and diversion of our efforts. Any such litigation or interference proceedings, regardless of the outcome, could be expensive and time consuming. Litigation could subject us to significant liabilities to third parties, requiring disputed rights to be licensed from third parties and/or requiring us to cease using certain technologies.

We also rely on trade secrets, know-how and technology that are not protected by patents to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, employees, and consultants. Any of these parties

could breach these agreements and disclose our confidential information, or our competitors may learn of the information in some other way. If any material trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our competitive position could be materially harmed.

RISKS RELATED TO OUR BUSINESS, INDUSTRY, STRATEGY AND OPERATIONS

If we fail to retain key personnel, our business could suffer.

We are dependent upon the principal members of our management and scientific staff. In addition, we believe that our future success in developing and marketing our products will depend on whether we can attract and retain additional qualified management and scientific personnel as well as a sales and marketing staff. There is strong competition for qualified personnel within the industry in which we operate, and we may not be able to attract and retain such personnel. As we have a small number of employees and we believe our products are unique and highly specialized, the loss of the services of one or more of the principal members of our management or scientific staff, or the inability to attract and retain additional personnel and develop expertise as needed, could have a material adverse effect on our results of operations and financial condition.

If we are subject to product liability suits, we may not have sufficient insurance to cover damages.

The testing, manufacturing, and marketing and sale of the products utilizing our technologies involve risks that product liability claims may be asserted against us and/or our licensees. Our current clinical trial and product liability insurance may not be adequate to cover damages resulting from product liability claims. Regardless of their merit or eventual outcome, product liability claims could require us to spend significant time, money and other resources to defend such claims, could result in decreased demand for our products and product candidates, or result in reputational harm, and could result in the payment of a significant damage award. Our product liability insurance coverage is subject to deductibles and coverage limitations and may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to acquire sufficient clinical trial or product liability insurance in the future on reasonable commercial terms, if at all.

Consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There has been consolidation in the pharmaceutical and biotechnology industries. Consolidation could result in the remaining companies having greater financial resources and technological capabilities, thus intensifying competition, and fewer potential collaboration partners or licensees for our product candidates. In addition, if a consolidating company is already doing business with any of our competitors, we could lose existing or potential future licensees or collaboration partners as a result of such consolidation.

If we or our licensees fail to comply with environmental laws and regulations, our or their ability to manufacture and commercialize products may be adversely affected.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We and our licensees are subject to federal, state and local laws and regulations in the U.S. and abroad governing the use, manufacture, storage, handling and disposal of such materials and waste products. We and they could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us or them for resulting injury or contamination, and the liability may exceed our or their ability to pay. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair the research, development or production efforts of our company or our licensees and harm our operating results.

If we or our licensees encounter problems with product manufacturing, there could be delays in product development or commercialization, which would adversely affect our future profitability.

Our ability and that of our licensees to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, and develop and commercialize our product candidates will depend, in part, upon our and our licensees' ability to manufacture our products and product candidates, either directly or through third parties, in accordance with FDA and other regulatory requirements. The manufacture, packaging and testing of our products and product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with applicable cGMP and comparable foreign requirements. Any change in a manufacturing process or procedure used for one of our products or product candidates, including a change in the location at which a product or product candidate is being manufactured or in the third-party manufacturer being

used, may require the FDA's and similar foreign regulatory entities' prior review and/or approval in accordance with applicable cGMP or other regulations. Additionally, the FDA and similar foreign regulatory entities may implement new standards, or change their interpretation and enforcement of existing standards, for the manufacture, packaging and testing of products at any time.

There are a limited number of manufacturers that operate under cGMP and other foreign regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Alimera has contracted with individual third-party manufacturers for the manufacture of ILUVIEN and its components. If any of Alimera's third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason or fail to comply with cGMP and comparable foreign requirements, Alimera may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities in a timely manner. Delays in the commercial production of ILUVIEN could delay or impair Alimera's marketing of ILUVIEN, which, in turn, could adversely affect Alimera's generation of net profits for us.

Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could result in sanctions being imposed on us or our collaborative partners, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions. In addition, we or our collaborative partners may not be able to manufacture our product candidates successfully or have a third party manufacture them in a cost-effective manner. If we or our collaborative partners are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products. We manufacture supplies in connection with pre-clinical or clinical studies conducted by us and our licensees. Our licensees have the exclusive rights to manufacture commercial quantities of products, once approved for marketing. Our and our licensees' reliance on third-party manufacturers entails risks, including:

- failure of third parties to comply with cGMP and other applicable U.S. and foreign regulations and to employ adequate quality assurance practices;
- inability to obtain the materials necessary to produce a product or to formulate the active pharmaceutical ingredient on commercially reasonable terms, if at all;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our or our licensees' control;
- termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or difficult; and
- inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

Problems associated with international business operations could affect our or our licensees' ability to manufacture and sell our products. If we encounter such problems, our or their costs could increase and development of products could be delayed.

We currently maintain offices and research and development facilities in the U.S. and the U.K., and our goal is to develop products for sale by us and our licensees in major world healthcare markets. Manufacturing of pharmaceutical products requires us or our licensees to comply with regulations regarding safety and quality and to obtain country and jurisdiction-specific regulatory approvals and clearances. We or our licensees may not be able to comply with such regulations or obtain or maintain needed regulatory approvals and clearances, or may be required to incur significant costs in doing so. In addition, our operations and future revenues may be subject to a number of risks associated with foreign commerce, including the following:

- staffing and managing foreign operations;
- political and economic instability;
- foreign currency exchange fluctuations;
- foreign tax laws, tariffs and freight rates and charges;
- timing and availability of export licenses;
- inadequate protection of intellectual property rights in some countries; and
- obtaining required government approvals.

Legislative or regulatory changes may adversely affect our business, operations and financial results.

Our industry is highly regulated and new laws, regulations and judicial decisions, and new interpretations of existing laws, regulations and judicial decisions, may adversely affect our business, operations and financial results.

U.S. federal and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA), represents one of the most significant healthcare reform measures in decades. The PPACA is intended to expand U.S. healthcare coverage primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. Several provisions of the PPACA could significantly reduce payments from Medicare and Medicaid for any product candidates that obtain marketing approval in the future. Federal and state legislatures within the U.S. and foreign governments will likely continue to consider changes in existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any products for which we may obtain regulatory approval; our ability to set a price that we believe is fair for our products; our ability to obtain coverage and reimbursement approval for a product; our ability to generate revenues and achieve or maintain profitability; or the level of taxes that we are required to pay.

In addition, other legislative changes have been proposed and adopted since PPACA. The Budget Control Act (BCA) of 2011 includes provisions to reduce the federal deficit. The BCA, as amended, resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013. More recent legislation extends reductions through 2024. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, and/or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the BCA, could have an adverse impact on our anticipated product revenues.

The FDAAA granted the FDA enhanced authority over products already approved for sale, including authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this relatively new authority could result in delays and increased costs during product development, clinical trials and regulatory review and approval, increased costs following regulatory approval to assure compliance with new post-approval regulatory requirements, and potential restrictions on the sale or distribution of approved products following regulatory approval.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, the July 9, 2012 reauthorization of the PDUFA extended by two months the period in which the FDA is expected to review and approve certain NDAs. Although the FDA has recently stated that it expects to meet PDUFA's updated timing goals, it has in the past provided its managers discretion to miss them due to heightened agency workload or understaffing in the review divisions. Accordingly, it remains unclear whether and to what extent the FDA will adhere to PDUFA timing goals in the future, which could delay approval and commercialization of our product candidates.

RISKS RELATED TO OUR COMMON STOCK

The price of our common stock may be volatile.

The price of our common stock (including common stock represented by CHESS Depositary Interests (CDIs)) may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The biotechnology sector, in particular, and the stock market generally are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the biotechnology industry, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock (and CDIs) and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- clinical trials and their results, and other product and technological developments and innovations;
- FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals;
- competitive factors, including the commercialization of new products in our markets by our competitors;

- advancements with respect to treatment of the diseases targeted by our product candidates;
- developments relating to, and actions by, our collaborative partners, including execution, amendment and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of payments to us;
- availability and cost of capital and our financial and operating results;
- actions with respect to pricing, reimbursement and coverage, and changes in reimbursement policies or other practices relating to our products or the pharmaceutical industry generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the biotechnology industry.

In addition, low trading volume in our common stock or our CDIs may increase their price volatility. Holders of our common stock and CDIs may not be able to liquidate their positions at the desired time or price. Finally, we will need to continue to meet the listing requirements of the NASDAQ Global Market, including the minimum stock price, and the Australian Securities Exchange (ASX), for our stock and CDIs to continue to be traded on those exchanges, respectively.

If the holders of our outstanding warrants and stock options exercise their warrants and options, ownership of our common stock holders may be diluted, and our stock price may decline.

As of September 30, 2014, we had outstanding warrants and options to acquire approximately 5.4 million shares of our common stock, or approximately 15.5% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of these warrants and stock options could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price.

We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

At the present time, we intend to use available funds to finance our operations. Accordingly, while payment of dividends rests within the discretion of our board of directors, no cash dividends on our common shares have been declared or paid by us and we have no intention of paying any such dividends in the foreseeable future.

Item 6. Exhibits

31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from pSivida Corp.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Comprehensive Income (Loss); (iii) Condensed Consolidated Statement of Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements

SIGNATURES

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

pSivida Corp.

Date: November 7, 2014

By: /s/ Paul Ashton
Name: Paul Ashton
Title: President and Chief Executive Officer

Exhibit 31.1

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

CERTIFICATIONS

I, Paul Ashton, certify that:

1. I have reviewed this quarterly report on Form 10-Q of pSivida Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2014

/s/ Paul Ashton

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

Exhibit 31.2

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

CERTIFICATIONS

I, Leonard S. Ross, certify that:

1. I have reviewed this quarterly report on Form 10-Q of pSivida Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2014

/s/ Leonard S. Ross

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

Exhibit 32.1

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 September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Ashton, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2014

/s/ Paul Ashton

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

Exhibit 32.2

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 September 30, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard S. Ross, Vice President, Finance of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 7, 2014

/s/ Leonard S. Ross

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