



November 12, 2013

## **pSivida Corp. Reports First Quarter 2014 Results**

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release, drug delivery products for treating eye diseases, today announced financial results for its first quarter ended September 30, 2013.

"We made excellent progress this quarter in advancing our own pipeline of products, including our lead development product, Medidur™ for posterior uveitis, now in a Phase III trial, and in enhancing our capital with \$10.8 million public offering of our common stock," said Dr. Paul Ashton, President and CEO of pSivida. "We look forward to continued growth in acceptance and sales in Europe of one of our licensed products, ILUVIEN® for chronic diabetic macular edema (DME), already being sold in the U.K. and Germany and slated to launch in France next year.

"The first of the two planned pivotal Phase III clinical trials for Medidur for posterior uveitis has commenced and continues on schedule. We expect that Medidur will treat posterior uveitis with an efficacy profile comparable to Retisert®, our FDA-approved implant for posterior uveitis currently being sold by Bausch & Lomb, and a side effect profile superior to Retisert. Interim data from a small investigator-sponsored Phase I/II study of Medidur for posterior uveitis patients were consistent with this hypothesis," Dr. Ashton continued. Posterior uveitis is an inflammatory disease of one of the layers of the eye. In the U.S., posterior uveitis affects approximately 175,000 people and is responsible for approximately 30,000 cases of legal blindness, making it the third largest cause of blindness.

"We are pleased that the U.K.'s National Institute for Health and Care Excellence (NICE) reversed its original views and issued final draft guidance that would significantly expand the availability of ILUVIEN in the U.K. and Wales. On issuance of final guidance expected this month, the U.K.'s National Health Service will provide reimbursement under a patient access scheme submitted by Alimera for pseudophakic patients (those who had previously undergone cataract surgery) with chronic DME that is insufficiently responsive to available therapies, a typically large subgroup of chronic DME patients," said Dr. Ashton. "However, we were very disappointed that our licensee Alimera Sciences received a complete response letter from the FDA on October 17, 2013 regarding ILUVIEN for DME. We expect to learn more about the potential for approval in the U.S. following a meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee scheduled by the FDA for January 27, 2014.

"Pre-clinical testing of potential products using Tethadur™, our second key technology platform, continues to be encouraging. Tethadur has the potential to deliver peptides, proteins and antibodies on a sustained basis to the eye. This could be mission critical to the development of BioSimilar and BioBetter for the treatment of ophthalmic disease in light of the importance of biologics in treatment of these diseases," continued Dr. Ashton. The use of Tethadur in certain ophthalmic applications is being evaluated under a funded evaluation agreement with a leading global biopharmaceutical company. Other major pharmaceutical companies are evaluating pSivida's technology platforms in other ophthalmic applications under funded agreements.

Revenues for the quarter ended September 30, 2013 totaled \$597,000 compared to \$553,000 for the prior year period. The increase was attributable to higher Retisert royalty income from Bausch & Lomb.

Net loss for the quarter ended September 30, 2013 was \$3.7 million, or \$0.14 per share, compared to a net loss of \$2.6 million, or \$0.11 per share, for the prior year quarter. The higher net loss in the first quarter of fiscal 2014 primarily reflected costs associated with the initiation of the Phase III clinical trial for Medidur for posterior uveitis.

At September 30, 2013, cash, cash equivalents and marketable securities increased to \$16.5 million compared to \$10.3 million at June 30, 2013, reflecting the addition of \$9.9 million in net proceeds from an underwritten public offering of common shares.

"Going forward, we expect our quarterly cash burn will continue to show some variability due to timing of clinical trial costs and payments from collaborating companies," said Dr. Ashton.

### **Today's Conference Call Reminder**

pSivida Corp. will host a live webcast and conference call today, November 12, 2013, at 4:30 pm ET. The conference call may be accessed by dialing (877) 312-7507 from the U.S. and Canada, or (631) 813-4828 from international locations. The

conference can also be accessed on the pSivida Corp. website at [www.psivida.com](http://www.psivida.com). A replay of the call will be available approximately two hours following the end of the call through November 19, 2013. The replay may be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID number 97230646.

## **About the Clinical Trials/Studies**

pSivida has initiated the first of two planned pivotal Phase III trials of Medidur for the treatment of posterior uveitis. These trials are expected to enroll a total of approximately 300 patients. The primary end point is the recurrence of uveitis within 12 months. pSivida will be permitted to reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN for DME conducted by Alimera.

The investigator-sponsored Phase I/II study of Medidur for posterior uveitis is a three-year study that will evaluate the safety and efficacy of Medidur in up to 12 patients with posterior uveitis. Interim results were measured on the twelve month anniversary of the start of enrollment. Through this period, none of the eyes receiving Medidur experienced a recurrence of uveitis and inflammation was reduced in all of these eyes. In contrast, all (untreated) control eyes had either a recurrence of uveitis or a worsening of inflammation. Furthermore, at the last follow-up visit reported in interim results, best corrected visual acuity (on the Early Treatment Diabetic Retinopathy Study eye chart) improved by an average of more than nine letters in treated eyes while untreated eyes declined by an average of one letter. Interim data showed that Medidur was well tolerated, and the observed safety profile was consistent with the short-term safety profile reported in clinical studies of ILUVIEN in DME eyes. Only one eye receiving Medidur measured an increase in intraocular pressure above the normal range.

## **About pSivida Corp.**

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release, drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™, including Tethadur™. The injectable, sustained release micro-insert ILUVIEN® for the treatment of chronic DME considered insufficiently responsive to available therapies, licensed to Alimera Sciences, Inc., is marketed in the U.K. and Germany and has also received marketing authorization in Austria, France, Portugal, and Spain and is awaiting authorization in Italy. Alimera has filed for ten additional EU country approvals through the Mutual Recognition Procedure. pSivida has instituted the first of two planned pivotal Phase III clinical trials for Medidur™ for the treatment of posterior uveitis, a chronic back-of-the-eye disease. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension, a product candidate on which Pfizer Inc. has an option. pSivida's FDA-approved Retisert®, licensed to Bausch & Lomb Incorporated, provides long-term, sustained drug delivery to treat posterior uveitis.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. 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: Alimera's ability to finance, achieve additional marketing approvals, obtain adequate pricing and reimbursement for, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; Alimera's ability to obtain regulatory approval for, and if approved, to finance, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the U.S.; the ability to finance, complete and achieve a successful outcome for Phase III trials for, and file and achieve marketing approvals for, Medidur for posterior uveitis, including achieving acceptable risk-to-benefit and safety profiles in light of the CRL for ILUVIEN; initiation, financing and success of Latanoprost Product Phase II trials and any exercise by Pfizer of its option; ability of Tethadur to successfully deliver proteins, peptides and other large biologic molecules; ability to develop product candidates and products and potential related collaborations; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; continued sales of Retisert; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty income; ability to, and to find partners to, develop and market products; termination of license agreements; competition and other developments affecting sales of products; market acceptance; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; consolidation in the pharmaceutical and biotechnology industries; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; credit and financial market conditions; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the SEC. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. 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. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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Google+: <https://plus.google.com/u/0/b/113754643626984244726/113754643626984244726/posts>

The President's Blog: <http://www.thechairmansblog.com/paul-ashton>

For more information on pSivida, visit [www.psivida.com](http://www.psivida.com).

**PSIVIDA CORP. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
**(In thousands except per share amounts)**

	<b>Three Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Revenues:		
Collaborative research and development	\$ 173	\$ 169
Royalty income	424	384
	<hr/>	<hr/>
Total revenues	597	553
	<hr/>	<hr/>
Operating expenses:		
Research and development	2,504	1,523
General and administrative	1,811	1,620
	<hr/>	<hr/>
Total operating expenses	4,315	3,143
	<hr/>	<hr/>
Loss from operations	(3,718)	(2,590)
	<hr/>	<hr/>
Other income (expense):		
Interest income	1	7
Other expense, net	-	(1)
	<hr/>	<hr/>
Total other income	1	6
	<hr/>	<hr/>
Loss before income taxes	(3,717)	(2,584)
Income tax benefit	30	33
	<hr/>	<hr/>
Net loss	<u>\$ (3,687)</u>	<u>\$ (2,551)</u>
	<hr/>	<hr/>
Net loss per share:		
Basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.11)</u>

Weighted average common shares outstanding:

Basic and diluted

25,91822,294

**PSIVIDA CORP. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(Unaudited)  
(In thousands)

	<b>September 30, 2013</b>	<b>June 30, 2013</b>
<b>Assets</b>		
<b>Current assets:</b>		
Cash, cash equivalents and marketable securities	\$ 16,454	\$ 10,273
Other current assets	2,658	2,191
	<hr/>	<hr/>
Total current assets	19,112	12,464
Intangible assets, net	3,300	3,430
Other assets	323	355
	<hr/>	<hr/>
<b>Total assets</b>	<b>\$ 22,735</b>	<b>\$ 16,249</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 2,169	\$ 2,565
Deferred revenue	688	738
	<hr/>	<hr/>
Total current liabilities	2,857	3,303
Deferred revenue	5,641	5,246
	<hr/>	<hr/>
<b>Total liabilities</b>	<b>8,498</b>	<b>8,549</b>
<b>Stockholders' equity:</b>		
Capital	280,597	270,438
Accumulated deficit	(267,345)	(263,658)
Accumulated other comprehensive income	985	920
	<hr/>	<hr/>
Total stockholders' equity	14,237	7,700
	<hr/>	<hr/>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 22,735</b>	<b>\$ 16,249</b>

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Source: pSivida Corp.

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