



May 13, 2014

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

### **Now Plans to Seek US approval of Medidur for Posterior Uveitis Based on One Phase III Trial**

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 third quarter ended March 31, 2014.

The Company now plans to seek U.S. approval for its lead development product, Medidur™ for posterior uveitis, based on data from one Phase III trial, with supplemental clinical data about the Company's proprietary inserter if ILUVIEN® for chronic diabetic macular edema (DME) is approved by the U.S. Food and Drug Administration (FDA). The Phase III trial has already begun, and enrollment is continuing. Medidur uses the same injectable sustained release micro-insert delivering the same dosage of the same drug as ILUVIEN, and pSivida will be able to reference the ILUVIEN New Drug Application (NDA) (including data from ILUVIEN's clinical trials) in a Medidur NDA. Posterior uveitis, an inflammatory disease of one of the inner lining the eye, affects approximately 175,000 people in the U.S., and is the third largest cause of blindness.

"Our revised regulatory strategy for Medidur has the potential to significantly accelerate U.S. commercial availability and reduce overall development costs. We remain optimistic that the FDA will approve ILUVIEN, which we believe will permit us to seek U.S. approval with data from a single Phase III trial for Medidur along with clinical data about our proprietary inserter. We plan to have a confirmatory meeting with the FDA with respect to our regulatory strategy as more data become available," said Dr. Paul Ashton, President and CEO of pSivida .

The Company recently presented the first peer-reviewed, in-vitro data for Tethadur™, pSivida's technology designed to provide sustained delivery of peptides, proteins and antibodies, demonstrating sustained delivery of Avastin with Tethadur. The study concluded that the release rate of antibodies such as Avastin is controllable over a wide range by adjusting the pore size and surface area of Tethadur. The Company plans to report the results of additional pre-clinical studies of Tethadur later in calendar 2014, potentially positioning the Company to file an Investigatory New Drug Application (IND).

"We are pleased with our studies of Tethadur to deliver biologics on a sustained basis and see exciting opportunities for potential products," continued Dr. Ashton. The Company is studying a number of applications of Tethadur to provide sustained delivery of biologics both systemically and directly to the back of the eye. A leading global biopharmaceutical company is evaluating the use of Tethadur in certain ophthalmic applications.

The NDA has been refiled for the Company's lead licensed product, ILUVIEN for chronic DME, and the FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of September 26, 2014. The resubmission responded to questions raised in the FDA's October 2013 complete response letter, provided a safety update, which included commercial experience with ILUVIEN in Europe, and addressed deficiencies noted in the methods and controls used for the drug product at the facility where ILUVIEN is manufactured. The Company's licensee, Alimera Sciences, entered into labeling discussions with the FDA.

ILUVIEN is commercially available to treat chronic DME insufficiently responsive to available therapies in the U.K. and Germany and is expected to be available in France in 2014. Following favorable regulatory action, ILUVIEN is now covered for National Health Service (NHS) patients with pseudophakic eyes (those that have had cataract surgery) in the U.K. and Scotland, subject to simple patient access schemes. ILUVIEN has marketing approvals in four additional EU countries and Alimera has filed for approval in eleven more EU countries.

Alimera recently entered into an exclusive agreement with Specialised Therapeutics Australia (STA) for the distribution of ILUVIEN in Australia and New Zealand. STA is responsible for regulatory and commercial matters, including marketing approval and reimbursement, in those countries.

"We are very pleased that the outlook for ILUVIEN has continued to brighten. Alimera has secured reimbursement in the U.K. and continued to expand ILUVIEN's geographic sales potential. We are particularly pleased with the refiled NDA, the new PDUFA date of September 26, 2014 and labeling discussions in the U.S.," said Dr. Ashton. "We are entitled to a \$25 million milestone payment if ILUVIEN is approved by the FDA and 20% of any net profits from sales by Alimera on a country-by-country

basis." Alimera recently entered into a loan agreement that provides for a \$25 million advance to pay the milestone if ILUVIEN is approved by the FDA on or before October 31, 2014 and certain other conditions are met.

Revenues for the quarter ended March 31, 2014 totaled \$2.0 million compared to \$513,000 for the prior year period, reflecting recognition in this year's quarter of \$1.5 million under a completed feasibility study agreement.

Net loss for the quarter ended March 31, 2014 was \$2.2 million, or \$0.08 per share, compared to a net loss of \$2.8 million, or \$0.12 per share, for the prior year quarter. The reduced net loss in the third quarter of fiscal 2014 primarily reflected the recognition of revenues in the fiscal 2014 third quarter noted above, partially offset by costs in the quarter associated with the Phase III clinical trial of Medidur for posterior uveitis, which had not commenced in last year's third quarter.

Revenues for the nine months ended March 31, 2014 totaled \$3.2 million compared to \$1.7 million for the nine months ended March 31, 2013. The Company reported a net loss of \$9.4 million, or \$0.35 per share, for the nine months ended March 31, 2014, compared to a net loss of \$8.0 million, or \$0.35 per share, for the same period of the prior year.

At March 31, 2014, cash, cash equivalents and marketable securities totaled \$21.3 million compared to \$15.7 million at December 31, 2013, primarily reflecting approximately \$6.9 million received from a March 2014 registered direct offering of common stock.

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

pSivida Corp. will host a live webcast and conference call today, May 13, 2014, 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 May 20, 2014. 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 40618782.

### **About the Clinical Trials**

pSivida has initiated a Phase III trial of Medidur for the treatment of posterior uveitis. If ILUVIEN for DME is approved by the FDA, pSivida plans to seek US approval of Medidur based on this trial and additional clinical data about pSivida's proprietary inserter. The ongoing Phase III trial is expected to enroll approximately 120 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 of ILUVIEN for chronic DME. If ILUVIEN is not approved by the FDA, the Company plans to file for FDA approval as originally planned.

### **About pSivida Corp.**

pSivida Corp., headquartered in Watertown, MA, is a leader in the development of sustained release, drug delivery products for treating eye diseases. 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 ~~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. Alimera resubmitted its NDA for ILUVIEN in March 2014 and the FDA has set a PDUFA goal date of September 26, 2014. pSivida has instituted a Phase III clinical trial of Medidur™ for the treatment of posterior uveitis, a chronic back-of-the-eye disease, which uses the same micro-insert as ILUVIEN. 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: the number of clinical trials necessary to support an NDA for Medidur; 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 chronic 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)**

	<u>Three Months Ended</u> <u>March 31,</u>		<u>Nine Months Ended</u> <u>March 31,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
Collaborative research and development	\$ 1,676	\$ 239	\$ 2,149	\$ 603
Royalty income	316	274	1,032	1,048
	<hr/>	<hr/>	<hr/>	<hr/>
Total revenues	1,992	513	3,181	1,651
	<hr/>	<hr/>	<hr/>	<hr/>
Operating expenses:				
Research and development	2,269	1,587	7,267	4,685
General and administrative	1,946	1,738	5,468	5,016
Gain on sale of property and equipment	(4)	-	(76)	-
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Total operating expenses	4,211	3,325	12,659	9,701
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Loss from operations	(2,219)	(2,812)	(9,478)	(8,050)
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Other income (expense), net:				

Interest income	1	3	3	14
Other expense, net	-	-	-	(2)
	<hr/>	<hr/>	<hr/>	<hr/>
Total other income	1	3	3	12
Loss before income taxes	(2,218)	(2,809)	(9,475)	(8,038)
Income tax benefit	31	15	87	85
	<hr/>	<hr/>	<hr/>	<hr/>
Net loss	<u>\$ (2,187)</u>	<u>\$ (2,794)</u>	<u>\$ (9,388)</u>	<u>\$ (7,953)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.12)</u>	<u>\$ (0.35)</u>	<u>\$ (0.35)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>27,672</u>	<u>23,297</u>	<u>26,842</u>	<u>22,960</u>

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

	<u>March 31,</u> <u>2014</u>	<u>June 30,</u> <u>2013</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash, cash equivalents and marketable securities	\$ 21,267	\$ 10,273
Other current assets	1,195	2,191
	<hr/>	<hr/>
Total current assets	22,462	12,464
Intangible assets, net	2,940	3,430
Other assets	619	355
	<hr/>	<hr/>
<b>Total assets</b>	<u>\$ 26,021</u>	<u>\$ 16,249</u>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 1,964	\$ 2,565
Deferred revenue	312	738
	<hr/>	<hr/>
Total current liabilities	2,276	3,303
Deferred revenue	5,388	5,246
Deferred rent	11	-
	<hr/>	<hr/>
<b>Total liabilities</b>	<u>7,675</u>	<u>8,549</u>
<b>Stockholders' equity:</b>		
Capital	290,373	270,438
Accumulated deficit	(273,046)	(263,658)
Accumulated other comprehensive income	1,019	920

Total stockholders' equity	<u>18,346</u>	<u>7,700</u>
<b>Total liabilities and stockholders' equity</b>	<u><b>\$ 26,021</b></u>	<u><b>\$ 16,249</b></u>

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Source: pSivida Corp.

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