



September 9, 2014

pSivida Corp. Reports Fourth Quarter and FY 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 fourth quarter and fiscal year ended June 30, 2014.

Advancing its strategy of becoming a specialty-pharma company, pSivida continued enrollment of the Phase III trial for its lead product candidate, Medidur™ for posterior uveitis, the third largest cause of blindness in the U.S. The Company expects to complete enrollment by the end of calendar Q1 2015. In a revised regulatory strategy, the Company plans to seek U.S. approval for Medidur based on data from a single, rather than two, Phase III trial, together with supplemental clinical data on its proprietary inserter. Medidur uses the same injectable, sustained-release micro-insert as ILUVIEN® for diabetic macular edema (DME). The FDA has agreed that pSivida can use much of the data, including clinical safety data, from the completed ILUVIEN Phase III trials to support an application for Medidur.

"Our revised regulatory strategy for Medidur has the potential to significantly accelerate the timing of approval of Medidur, reducing overall development costs and advancing U.S. commercial availability. We plan to meet with the FDA to confirm our strategy. Because Medidur delivers the same drug as both ILUVIEN and Retisert® (our partnered, FDA-approved inserter for the treatment of posterior uveitis) but in the lower dose delivered by ILUVIEN, we are optimistic that Medidur will show efficacy comparable to Retisert, but with the more favorable risk/benefit profile and decreased side effects of ILUVIEN," said Dr. Paul Ashton, Ph.D., President and CEO of pSivida. "Interim data from an investigator-sponsored study reported earlier supported this view. Medidur would be our fourth approved product based on our Durasert™ platform technology."

The Company also continued to advance the pre-clinical development of Tethadur™, its platform technology designed to provide sustained delivery of peptides and proteins (including antibodies). The first peer-reviewed, in-vitro data for Tethadur presented earlier this year demonstrated the sustained delivery of Avastin® and the ability of Tethadur to provide a wide range of antibody release rates.

"We are pleased with our studies of Tethadur to deliver biologics on a sustained basis. We believe that our ability to control release rate by varying the pore size and surface area of Tethadur could permit sustained delivery of antibodies that currently must be delivered by frequent injection," continued Dr. Ashton. "We see exciting opportunities, alone and in conjunction with Durasert, to provide sustained delivery of biologics, both directly to the target area to treat conditions such as wet and dry age-related macular degeneration (AMD) and osteoarthritis, and on a systemic basis. We plan to report the results of additional pre-clinical studies of Tethadur later in calendar 2014, which could be the basis for our first Investigatory New Drug Application (IND) using Tethadur."

"We are very optimistic for our lead partnered product, ILUVIEN for DME. The New Drug Application (NDA) was refiled earlier this year, with a resulting Prescription Drug User Fee Act (PDUFA) goal date of September 26, 2014. Our licensee, Alimera Sciences, entered into labeling discussions with the FDA, and we await the FDA's decision with anticipation. We are entitled to a \$25.0 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."

"In Europe, ILUVIEN's geographic footprint continues to expand," noted Dr. Ashton. ILUVIEN has now been approved in ten EU countries for the treatment of chronic DME insufficiently responsive to available therapies, and approval is pending in seven others. Alimera is selling ILUVIEN in the U.K. and Germany and expects to launch in France and Portugal in late 2014. ILUVIEN's sales in the U.K. and Scotland responded favorably to regulatory action earlier this year making ILUVIEN available through the National Health Service (NHS) to patients who have had cataract surgery. In addition, Australia and New Zealand were added to ILUVIEN's potential reach with the execution of an exclusive regulatory and distribution agreement for those countries.

"We enhanced our liquidity in the last fiscal year with the sale of common stock, ending the year with \$18.3 million," concluded Dr. Ashton.

Revenues for the year ended June 30, 2014 totaled \$3.5 million compared to \$2.1 million for the prior fiscal year. The increase was primarily attributable to recognition of \$1.5 million of consideration from a feasibility study agreement upon resolution of a

contingency.

Operating expenses for the year ended June 30, 2014 totaled \$17.0 million compared to \$14.2 million for the year ended June 30, 2013. The increase was principally due to research and development costs of the Medidur Phase III clinical trial that commenced in the quarter ended June 30, 2013.

Net loss for the year ended June 30, 2014 was \$13.4 million, or \$0.49 per share, compared to a net loss of \$11.9 million, or \$0.52 per share, for the prior fiscal year.

Revenues for the quarter ended June 30, 2014 totaled \$292,000 compared to \$492,000 for the quarter a year earlier. The Company reported a net loss of \$4.0 million, or \$0.14 per share, for the quarter ended June 30, 2014, compared to a net loss of \$3.9 million, or \$0.17 per share, for the same period of the prior year.

At June 30, 2014, cash, cash equivalents and marketable securities totaled \$18.3 million compared to \$10.3 million at the same time last year.

Today's Conference Call Reminder

pSivida Corp. will host a live webcast and conference call today, September 9, 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. A replay of the call will be available approximately two hours following the end of the call through September 16, 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 97522257.

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™. pSivida has instituted a pivotal Phase III clinical trial for its lead product candidate, Medidur™ for treatment of the chronic, back-of-the-eye disease posterior uveitis. Medidur uses the same injectable, sustained release micro-insert as pSivida's lead licensed product, ILUVIEN® for the treatment of DME, licensed to Alimera Sciences, Inc. ILUVIEN is marketed in the U.K. and Germany, has also received marketing authorization in eight other EU countries and is pending approval in seven more EU countries under the Mutual Recognition Procedure, for the treatment of chronic DME considered insufficiently responsive to available therapies. ILUVIEN for DME is currently under review by the FDA with a PDUFA goal date of September 26, 2014. pSivida's FDA-approved Retisert®, an implant which provides long-term, sustained drug delivery to treat posterior uveitis, is licensed to and sold by Bausch & Lomb Incorporated. pSivida's pre-clinical research is focused on ocular and systemic delivery of biologics and treatment of wet and dry age-related macular degeneration, osteoarthritis and glaucoma.

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 seek FDA approval for Medidur for posterior uveitis, which may depend on whether or not the FDA approves ILUVIEN, and outcome of the clinical trial(s); 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.; Alimera's ability to pay the \$25.0 million milestone due upon FDA approval; our ability to finance, complete and achieve a successful outcome for clinical trials for, and file and achieve marketing approvals for, Medidur, including achieving acceptable risk-to-benefit and safety profiles in light of the CRL for ILUVIEN; 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.

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

	<u>Three Months Ended</u> <u>June 30,</u>		<u>Year Ended</u> <u>June 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
Collaborative research and development	\$ 6	\$ 177	\$ 2,155	\$ 780
Royalty income	286	315	1,318	1,363
	<u>292</u>	<u>492</u>	<u>3,473</u>	<u>2,143</u>
Total revenues				
Operating expenses:				
Research and development	2,306	2,320	9,573	7,005
General and administrative	2,000	2,153	7,468	7,169
Gain on sale of property and equipment	(2)	-	(78)	-
	<u>4,304</u>	<u>4,473</u>	<u>16,963</u>	<u>14,174</u>
Total operating expenses				
Loss from operations	<u>(4,012)</u>	<u>(3,981)</u>	<u>(13,490)</u>	<u>(12,031)</u>
Other income (expense), net:				
Interest income	3	2	6	16
Other expense, net	(1)	-	(1)	(2)
	<u>2</u>	<u>2</u>	<u>5</u>	<u>14</u>
Total other income				
Loss before income taxes	(4,010)	(3,979)	(13,485)	(12,017)
Income tax benefit	43	32	130	117
	<u>(3,967)</u>	<u>(3,947)</u>	<u>(13,355)</u>	<u>(11,900)</u>
Net loss				
Net loss per share:				
Basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.17)</u>	<u>\$ (0.49)</u>	<u>\$ (0.52)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>29,256</u>	<u>23,297</u>	<u>27,444</u>	<u>23,044</u>

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

	<u>June 30,</u> <u>2014</u>	<u>June 30,</u> <u>2013</u>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 18,278	\$ 10,273
Other current assets	1,064	2,191
Total current assets	19,342	12,464
Intangible assets, net	2,765	3,430
Other assets	564	355
Total assets	<u>\$ 22,671</u>	<u>\$ 16,249</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,988	\$ 2,565
Deferred revenue	138	738
Total current liabilities	2,126	3,303
Deferred revenue, less current portion	5,584	5,246
Deferred rent	37	-
Total liabilities	<u>7,747</u>	<u>8,549</u>
Stockholders' equity:		
Capital	290,893	270,438
Accumulated deficit	(277,013)	(263,658)
Accumulated other comprehensive income	1,044	920
Total stockholders' equity	<u>14,924</u>	<u>7,700</u>
Total liabilities and stockholders' equity	<u>\$ 22,671</u>	<u>\$ 16,249</u>

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