



February 5, 2015

pSivida Corp. Reports Second Quarter FY 2015 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 second quarter ended December 31, 2014.

pSivida's lead licensed product ILUVIEN® has made significant progress. It is scheduled to commence sales in the U.S. this quarter following FDA approval in September for patients with diabetic macular edema (DME) previously treated with a course of corticosteroids without a clinically significant rise in intraocular pressure. In the EU, ILUVIEN was launched in Portugal in January and has been sold in the U.K. and Germany since 2013. Since the fiscal 2015 first quarter, ILUVIEN has been approved in 8 more EU countries, bringing the total EU marketing approvals to 15 with two others pending, for treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. ILUVIEN has been sublicensed in Australia and New Zealand. pSivida is entitled to 20% of the net profits from sales of ILUVIEN by its licensee on a country-by-country, quarter-by-quarter basis and 20% of royalties and 33% of other amounts from sublicenses of ILUVIEN.

"We are really looking forward to the upcoming launch of ILUVIEN in the U.S. With its three-year treatment duration, ILUVIEN should provide a valuable alternative for the treatment of DME patients who now face injections as frequently as monthly with anti-VEGF therapy, particularly the many patients whose disease is not optimally managed with that therapy," said Paul Ashton, Ph.D., President and CEO of pSivida.

During its fiscal 2015 second quarter, pSivida received the \$25 million milestone payment as a result of the approval of ILUVIEN by the U.S. Food and Drug Administration (FDA). "With over \$35 million in cash at the end of our second quarter, our cash resources position us well to continue our product development programs into 2017 without any potential future contribution from ILUVIEN."

pSivida's lead development product, Medidur™ for the treatment of posterior uveitis, is being tested in a pivotal Phase III trial. Enrollment is expected to be completed around the end of March 2015. With a primary end-point of recurrence of disease at 12 months, top-line data from the trial is anticipated in the first half of calendar 2016. The Company expects to review its plan with the FDA this quarter to seek U.S. regulatory approval based on data from this single trial, rather than two trials, together with supplemental clinical data on pSivida's proprietary inserter. Medidur uses the same injectable, sustained-release micro-insert as ILUVIEN for DME (same design, same drug, same polymer, same release rate). 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.

pSivida's pre-clinical development program is focused on its Durasert™ and Tethadur™ platform technologies. Durasert is designed to provide long-term sustained release of drugs. Different generations of Durasert are the basis of pSivida's three approved products, as well as Medidur. Tethadur is designed to provide sustained delivery of antibodies and other proteins. The Company's research is focused on back-of-the-eye diseases, including wet and dry age-related macular degeneration (AMD) and glaucoma, as well as osteoarthritis and other diseases.

"We continue to work on evolving our Durasert technology. We are seeking to develop a micro-insert to deliver repurposed approved drugs that have shown promise for the treatment of dry AMD. We are working with the Hospital for Special Surgery to develop an implant to provide sustained delivery of a steroid for the treatment of osteoarthritis of the knee. We also continue development of our Tethadur technology. We remain optimistic about the ability of Tethadur to solve the challenge of sustained delivery of biologics, which comprise many of today's top-selling pharmaceuticals, most of which must be delivered by frequent injections. We are working to develop our own products where the perceived risk, cost and opportunity are appropriate, while seeking to continue to leverage our technologies through collaborative efforts where expertise and/or cost make that a preferable product development approach."

Results for the FY2015 Second Quarter. Revenues for the quarter ended December 31, 2014 totaled \$521,000 compared to \$592,000 for the prior year's second quarter. The decrease was due to lower revenues from funded technology evaluation agreements, partially offset by higher Retisert royalty income.

Operating expenses for the three months ended December 31, 2014 totaled \$4.6 million compared to \$4.1 million a year

earlier. The increase included CRO costs for the Medidur Phase III program and stock-based compensation.

Net loss for the quarter ended December 31, 2014 was \$4.1 million, or \$0.14 per share, compared to a net loss of \$3.5 million, or \$0.13 per share, for the prior year quarter.

Revenues for the six months ended December 31, 2014 totaled \$25.8 million compared to \$1.2 million for the six months ended December 31, 2013. The increase reflected the \$25.0 million milestone for FDA approval of ILUVIEN recorded in the fiscal 2015 first quarter.

Operating expenses for the six months ended December 31, 2014 totaled \$9.2 million compared to \$8.4 million for the same period of the prior year, with the increase primarily due to costs of the Medidur clinical development program and stock-based compensation.

Net income for the six months ended December 31, 2014 totaled \$16.5 million, or \$0.54 per diluted share, compared to a net loss of \$7.2 million, or \$0.27 per share for the six months ended December 31, 2013.

At December 31, 2014, cash, cash equivalents and marketable securities totaled \$35.7 million. The Company's quarterly cash burn is expected to vary from quarter to quarter based on timing and amounts of cash payments, including CRO payments, and cash receipts under collaboration agreements.

Today's Conference Call Reminder

pSivida Corp. will host a live webcast and conference call today, February 5, 2015, at 4:30pm 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 February 12, 2015. 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 75075675.

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 utilizing its core Durasert™ and Tethadur™ platform technology systems. pSivida's lead product candidate, Medidur™ for treatment of posterior uveitis, is being studied in a pivotal Phase III clinical trial. Medidur uses the same injectable, sustained release micro-insert as pSivida's lead licensed product, ILUVIEN® for the treatment of DME. ILUVIEN has been approved in the U.S., is marketed in the U.K., Germany and Portugal and has marketing authorization in 12 other EU countries, with two EU approvals still pending. pSivida's other licensed product, Retisert®, an implant that treats posterior uveitis, is sold in the U.S. pSivida's pre-clinical research is focused on ocular and systemic delivery of biologics and drugs to treat wet and dry age-related macular degeneration, glaucoma, osteoarthritis and other diseases.

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. 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 include 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 flucinolone 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 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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Twitter: <https://twitter.com/pSividaCorp>

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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>December 31,</u>		<u>Six Months Ended</u> <u>December 31,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
Collaborative research and development	\$ 164	\$ 300	\$ 25,245	\$ 473
Royalty income	357	292	583	716
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Total revenues	521	592	25,828	1,189
Operating expenses:				
Research and development	2,767	2,494	5,551	4,998
General and administrative	1,870	1,711	3,604	3,522
Gain on sale of property and equipment	-	(72)	-	(72)
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Total operating expenses	4,637	4,133	9,155	8,448
(Loss) income from operations	(4,116)	(3,541)	16,673	(7,259)
Interest income	3	1	6	2
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(Loss) income before income taxes	(4,113)	(3,540)	16,679	(7,257)
Income tax benefit (expense)	38	26	(188)	56
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Net (loss) income	<u>\$ (4,075)</u>	<u>\$ (3,514)</u>	<u>\$ 16,491</u>	<u>\$ (7,201)</u>
Net (loss) income per share:				
Basic	<u>\$ (0.14)</u>	<u>\$ (0.13)</u>	<u>\$ 0.56</u>	<u>\$ (0.27)</u>
Diluted	<u>\$ (0.14)</u>	<u>\$ (0.13)</u>	<u>\$ 0.54</u>	<u>\$ (0.27)</u>

Weighted average common shares outstanding:

Basic	<u>29,367</u>	<u>26,953</u>	<u>29,345</u>	<u>26,435</u>
Diluted	<u>29,367</u>	<u>26,953</u>	<u>30,618</u>	<u>26,435</u>

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

	<u>December 31,</u> <u>2014</u>	<u>June 30,</u> <u>2014</u>
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 35,686	\$ 18,278
Other current assets	1,662	1,064
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Total current assets	37,348	19,342
Intangible assets, net	2,301	2,765
Other assets	531	564
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Total assets	<u>\$ 40,180</u>	<u>\$ 22,671</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,204	\$ 1,988
Deferred revenue	69	138
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Total current liabilities	2,273	2,126
Deferred revenue	5,584	5,584
Deferred rent	48	37
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Total liabilities	<u>7,905</u>	<u>7,747</u>
Stockholders' equity:		
Capital	291,854	290,893
Accumulated deficit	(260,522)	(277,013)
Accumulated other comprehensive income	943	1,044
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Total stockholders' equity	<u>32,275</u>	<u>14,924</u>
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Total liabilities and stockholders' equity	<u>\$ 40,180</u>	<u>\$ 22,671</u>

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Source: pSivida Corp.

