

## pSivida Corp. Reports First Quarter Fiscal Year 2013 Results

WATERTOWN, Mass.--(BUSINESS WIRE)-- pSivida Corp. (NASDAQ: PSDV)(ASX: PVA), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, today announced financial results for its first quarter ended September 30, 2012.

"We are very pleased that the FDA has cleared us to proceed directly to two pivotal Phase III clinical trials of our lead development product, an injectable micro-insert for posterior uveitis," said Dr. Paul Ashton, President and CEO. "We intend these trials, which we plan to begin next year, to form the basis for a future NDA submission. We are also pleased with the progress and initial results of pre-clinical studies of applications of Tethadur<sup>TM</sup>, our protein/antiody delivery technology platform.

"With respect to the posterior uveitis micro-insert, the FDA's decision to allow us to reference much of the ILUVIEN® data for diabetic macular edema (DME), including the clinical safety data, from Alimera Sciences' already-completed pivotal Phase III clinical trials, has the potential to both simplify any future NDA submission and to shorten development time. We are planning to target enrollment of a total of 300 patients in our two trials, with a primary end point of recurrence of uveitis at 12 months. Because this development product uses the same micro-insert used in ILUVIEN for DME, which delivers a smaller dosage of the same drug as our Retisert® product already approved for posterior uveitis, we expect our trials will show efficacy similar to Retisert but with a side-effect profile in uveitis patients comparable to that seen in DME patients. We are optimistic therefore that our micro-insert will be efficacious for posterior uveitis, with a favorable risk/benefit profile and fewer side effects compared to Retisert," continued Dr. Ashton.

Tethadur, the Company's protein/anti-body delivery platform, has the potential to provide sustained release of peptides and proteins in many therapeutic areas and is currently being evaluated in ophthalmology under an agreement with a leading global biopharmaceutical company. In the ophthalmic area, a sustained delivery system like Tethadur for these types of molecules could offer a significant clinical advance because they must currently be injected into the eye every one or two months.

Regarding the European commercialization of ILUVIEN for DME, Alimera Sciences, pSivida's licensee, has announced a planned direct commercial launch in three EU countries in 2013, with Germany expected in the first quarter, the United Kingdom in the second quarter and France in the third quarter. ILUVIEN has received marketing authorization in the United Kingdom, Austria, Portugal, France and Germany, and has been recommended for marketing authorization in Italy and Spain, for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Alimera completed a \$40 million financing to proceed with the direct commercialization of ILUVIEN for DME in Germany, the U.K. and France. Alimera has estimated that there are approximately one million people suffering from DME in the seven EU countries where marketing authorization has either been received or recommended.

Alimera also announced that it intends to resubmit the NDA for ILUVIEN for DME to the FDA during the first quarter of 2013. Alimera further announced that using data from its two previously completed pivotal Phase III clinical trials, the resubmission will focus on the population of patients with chronic DME, the same group for which marketing approval for ILUVIEN has been granted in various EU countries. Approval in the U.S. would entitle pSivida to a \$25 million milestone payment and 20% of net profits, as defined, from U.S. sales of ILUVIEN by Alimera.

The investigator-sponsored Phase I/II dose-escalation study of pSivida's bioerodible, injectable latanoprost micro-insert for glaucoma and ocular hypertension is ongoing. Pfizer has an exclusive option under various circumstances to license the development and commercialization worldwide of this micro-insert for human ophthalmic disease other than uveitis.

Revenues for the fiscal 2013 first quarter were \$553,000 compared to \$1.7 million for the first quarter a year earlier. The fiscal 2012 first quarter included \$1.1 million of revenue recognition from the termination of a 2008 nutraceutical field of use license. pSivida reported a net loss of \$2.6 million, or \$0.11 per share, for the first quarter ended September 30, 2012, compared to a net loss of \$2.4 million, or \$0.12 per share, for the first quarter of the prior year.

At September 30, 2012, cash, cash equivalents and marketable securities totaled \$17.6 million, reflecting \$4.7 million in net proceeds from an August registered direct offering of shares of common stock and warrants.

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

pSivida Corp. will host a live webcast and conference call today. November 8, 2012, at 4:30 pm ET. The conference call may be accessed by dialing (877) 303-9236 from the U.S. and Canada, or (760) 666-3569 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 November 15, 2012. 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 59823674.

#### 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™. The injectable, sustained release micro insert ILUVIEN® for the treatment of chronic DME, licensed to Alimera Sciences, Inc., has received marketing authorization in Austria, France, Germany, Portugal and the U.K. and is awaiting authorization in Italy and Spain, ILUVIEN for DME has not been approved in the US, pSivida plans to institute pivotal Phase III clinical trials for the treatment of posterior uveitis with the same micro-insert as ILUVIEN for DME. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension. pSivida's two FDA-approved products, Retisert® and Vitrasert®, are implants that provide long-term, sustained drug delivery to treat two other chronic diseases of the retina.

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, successfully commercialize and achieve market acceptance of, and generate revenues to pSivida from, ILUVIEN for DME in the EU; Alimera's resubmission of its NDA for ILUVIEN for DME and its 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.; financing and success of Phase III posterior uveitis trials including efficacy, side effects and risk/benefit profile of the posterior uveitis micro-insert; initiation, financing and success of Latanoprost Product Phase II trials and exercise by Pfizer of its option; development of products using Tethadur and BioSilicon; initiation and completion of clinical trials and obtaining regulatory approval of product candidates; adverse side effects; ability to attain profitability; ability to obtain additional capital; further impairment of intangible assets; fluctuations in operating results; decline in royalty revenues; 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; possible influence by Pfizer; 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. 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.

Three Months Ended

# **PSIVIDA CORP. AND SUBSIDIARIES** CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands except per share amounts)

	September 30,			
	2012		2011	
Revenues:				
Collaborative research and development	\$	169	\$	1,461
Royalty income		384		198
Total revenues		553		1,659

Operating expenses:

Research and development General and administrative	1,523 1,620	2,129 2,061
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Total operating expenses	 3,143	 4,190
Loss from operations	 (2,590)	 (2,531)
Other income (expense):		
Change in fair value of derivatives	-	42
Interest income	7	9
Other expense, net	(1)	(2)
Total other income	 6	49
Loss before income taxes	(2,584)	(2,482)
Income tax benefit	33	55
Net loss	\$ (2,551)	\$ (2,427)
Net loss per share:		
Basic and diluted	\$ (0.11)	\$ (0.12)
Weighted average common shares outstanding:		
Basic and diluted	22,294	20,757
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# PSIVIDA CORP. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited) (In thousands)

		September 30, 2012		June 30, 2012	
Assets Current assets: Cash, cash equivalents and marketable securities Other current assets	\$	17,646 1,254	\$	14,571 1,388	
Total current assets Intangible assets, net Other assets		18,900 4,078 361		15,959 4,226 412	
Total assets	\$	23,339	\$	20,597	
Liabilities and stockholders' equity Current liabilities: Accounts payable and accrued expenses Deferred revenue	\$	1,067 2,395	\$	1,002 2,176	
Total current liabilities		3,462		3,178	

Deferred revenue	3,714	3,783
Total liabilities	7,176	6,961
Stockholders' equity: Capital Accumulated deficit Accumulated other comprehensive income	 269,463 (254,309) 1,009	264,452 (251,758) 942
Total stockholders' equity	 16,163	13,636
Total liabilities and stockholders' equity	\$ 23,339	\$ 20,597

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