# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 12, 2011

# **PSIVIDA CORP.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 000-51122 (Commission File Number) 26-2774444 (IRS Employer Identification No.)

400 Pleasant Street Watertown, MA 02472

(Address of Principal Executive Offices) (Zip Code)

(617) 926-5000 (Registrant's Telephone Number, Including Area Code)

Not applicable (Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

D Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02. Results of Operations and Financial Condition.

On September 12, 2011, pSivida Corp. issued a press release announcing its fiscal fourth quarter and fiscal year ended June 30, 2011 results and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in this report, including Items 2.02 and 9.01 and Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

#### Item 9.01 Financial Statements and Exhibits

# (d) Exhibits.

The following Exhibit is furnished with this report on Form 8-K:

No. Description

99.1 Press release of pSivida Corp. dated September 12, 2011.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# PSIVIDA CORP.

Date: September 12, 2011

By: <u>/s/ Lori Freedman</u>

Lori Freedman, Vice President, Corporate Affairs, General Counsel and Secretary



## PSIVIDA CORP. REPORTS FOURTH QUARTER AND FISCAL YEAR 2011 RESULTS

WATERTOWN, MA – September 12, 2011 — pSivida Corp. (NASDAQ: PSDV, ASX: PVA), a leader in developing sustained release, drug delivery products for treatment of back-of-the-eye diseases, including clinical stage product candidates for the treatment of diabetic macular edema (DME), uveitis affecting the posterior segment of the eye (posterior uveitis) and glaucoma, today announced financial results for its fourth quarter and fiscal year ended June 30, 2011.

At June 30 2011, cash, cash equivalents and marketable securities totaled \$24.1 million compared to \$17.6 million at June 30, 2010.

"We believe we have made very good progress this year in developing our clinical stage product pipeline with both our partnered and unpartnered programs," said Paul Ashton, President and CEO. "ILUVIEN® for DME, partnered with Alimera Sciences, is well along, with action by the FDA expected in November. We are very optimistic about this product, particularly in light of the 3-year data and subgroup analysis provided to the FDA in May."

"In addition to ILUVIEN, we have two other product candidates in clinical trials. We announced earlier today the opening of an Investigational New Drug Application (IND) for an investigator-sponsored trial in posterior uveitis. This trial will use inserts of the same design as those used in the ILUVIEN for DME trials. Our collaboration agreement with Alimera allows us to reference the DME regulatory filings, including the NDA (including clinical, safety and stability data from the Phase III trials), which provides the potential for an abbreviated clinical development and regulatory approval process. We also announced in June that the bioerodilble latanoprost insert for glaucoma (partnered with Pfizer) is in a clinical trial," said Dr. Ashton.

On May 12, 2011, Alimera resubmitted the NDA for ILUVIEN for DME, an injectable Durasert<sup>™</sup> insert delivering the corticosteroid fluocinolone acetonide (FAc), to respond to the FDA's Complete Response Letter. Alimera has reported that it expects a response from the FDA in November 2011.

Under the June 2011 amended and restated collaboration agreement with Pfizer, the Company granted Pfizer an exclusive option under various circumstances to license the development and commercialization worldwide of an injectable, bioerodible sustained release insert delivering latanoprost for human ophthalmic disease or conditions other than uveitis. Pfizer made an upfront payment of \$2.3 million, and the Company has the right to develop this product candidate through Phase II clinical trials. In June 2011, the Company announced a

Phase I/II dose escalating study designed to assess the safety and efficacy of this insert in patients with elevated intraocular pressure.

On September 12, 2011, the Company announced the opening of an IND for an investigator-sponsored Phase I/II clinical trial to assess the safety and efficacy of the Company's injectable, sustained release insert delivering FAc for the treatment of uveitis affecting the posterior segment of the eye. The inserts in the trial deliver the high and low dose of FAc studied in the Phase III trials of ILUVIEN for DME. The Company licensed Alimera the right to use this insert for the treatment and prevention of eye diseases in humans other than uveitis.

Revenues for the year ended June 30, 2011 totaled \$5.0 million compared to \$23.1 million for the year ended June 30, 2010. Fiscal 2011 revenues were primarily attributable to the June 2011 amendment and restatement of the Company's collaboration agreement with Pfizer, while the prior year's revenues were predominantly due to payment in full by Alimera of a \$15.0 million conditional note and recognition of deferred revenue from the Alimera agreement, which was completed in the fiscal 2010 second quarter. For the year ended June 30, 2011, the Company reported a net loss of \$8.6 million, or \$0.44 per share, compared to net income of \$8.8 million, or \$0.46 per diluted share, for the prior fiscal year.

Revenues for the fiscal 2011 fourth quarter were \$3.7 million compared to \$15.7 million a year earlier, reflecting revenues from the Pfizer agreement in fiscal 2011 and the Alimera note repayment in the fiscal 2010 quarter. The Company reported a net loss of \$140,000, or \$0.01 per share, for the fourth quarter ended June 30, 2011, compared to net income of \$13.1 million, or \$0.68 per diluted share, for the fourth quarter of the prior year.

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

pSivida Corp. will host a live webcast and conference call today, September 12, 2011, at 4:30 pm ET. The conference call may be accessed by dialing (866) 203-2528 from the U.S. and Canada, or (617) 213-8847 from international locations, passcode 80736748. The conference can also be accessed on the pSivida Corp. website at <u>www.psivida.com</u>. A replay of the call will be available approximately two hours following the end of the call through September 19, 2011. The replay may be accessed by dialing (888) 286-8010 within the U.S. and Canada or (617) 801-6888 from international locations, passcode 46828003.

#### 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<sup>™</sup> and BioSilicon<sup>™</sup>. ILUVIEN<sup>®</sup> for the treatment of Diabetic Macular Edema, which is licensed to Alimera Sciences, Inc., is pSivida's most advanced product candidate and is currently under review by the U.S. Food and Drug Administration. An investigator-sponsored Investigational New Drug application opened for an injectable insert to treat posterior uveitis of the same design as ILUVIEN for DME, and an investigator-sponsored trial is ongoing for an injectable, bioerodible insert to treat glaucoma and ocular hypertension. pSivida's two FDA-approved products, Retisert<sup>®</sup> and Vitrasert<sup>®</sup>, 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: ability to obtain additional capital if needed; future losses; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; decline of royalty income from Bausch & Lomb; Alimera's ability to obtain regulatory approval of ILUVIEN; Alimera's ability to successfully commercialize ILUVIEN if approved; risk/benefit profile of ILUVIEN; timeliness of approval, if any, of ILUVIEN and any limitations on uses thereof; ability to complete clinical trials, reference data and obtain regulatory approval of other product candidates; ability to find partners to develop and market products; termination of license agreements; competition; market acceptance of products and product candidates; reduction in use of products as a result of future publications; ability to protect intellectual property or infringement of others' intellectual property; 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 through exercise of outstanding warrants and stock options or future stock issuances; possible influence by Pfizer; ability to pay any registration penalties; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements will not be realized.

#### **Released by:**

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

		Three Months Ended June 30,		Year Ended June 30,	
P		2010	2011	2010	
Revenues:	¢ 2.204	¢15 000	¢ 0.010	¢00 570	
Collaborative research and development	\$ 3,394 321	\$15,328 394	\$ 3,612	\$22,570	
Royalty income			1,353	483	
Total revenues	3,715	15,722	4,965	23,053	
Operating expenses:					
Research and development	1,851	1,785	6,864	6,994	
General and administrative	2,172	1,763	8,104	6,968	
Total operating expenses	4,023	3,548	14,968	13,962	
Operating (loss) income	(308)	12,174	(10,003)	9,091	
Other income (expense):				<u> </u>	
Change in fair value of derivatives	10	870	1,140	(339)	
Interest income	11	25	30	27	
Other expense, net	(2)	(11)	(13)	(3)	
Total other income (expense)	19	884	1,157	(315)	
(Loss) income before income taxes	(289)	13,058	(8,846)	8,776	
Income tax benefit (expense)	149	15	218	(23)	
Net (loss) income	\$ (140)	\$13,073	\$ (8,628)	\$ 8,753	
Net (loss) income per share:					
Basic	\$ (0.01)	\$ 0.71	\$ (0.44)	\$ 0.48	
Diluted	\$ (0.01)	\$ 0.68	\$ (0.44)	\$ 0.46	
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	
Weighted average common shares outstanding:					
Basic	20,745	18,531	19,489	18,405	
Diluted	20,745	19,217	19,489	18,895	

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

	June 30, 2011	June 30, 2010
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 24,128	\$ 17,565
Other current assets	1,238	1,469
Total current assets	25,366	19,034
Intangible assets, net	21,564	23,877
Other assets	183	103
Total assets	\$ 47,113	\$ 43,014
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,650	\$ 1,545
Deferred revenue	3,212	79
Derivative liabilities	170	1,310
Total current liabilities	5,032	2,934
Deferred revenue	4,635	6,817
Deferred tax liabilities	13	222
Total liabilities	9,680	9,973
Stockholders' equity:		
Capital	262,927	250,815
Accumulated deficit	(226,923)	(218,295)
Accumulated other comprehensive income	1,429	521
Total stockholders' equity	37,433	33,041
Total liabilities and stockholders' equity	\$ 47,113	\$ 43,014