## 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 24, 2012

## **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)                 |
|--|
| 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 24, 2012, pSivida Corp. issued a press release announcing its fiscal fourth quarter and fiscal year ended June 30, 2012 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 24, 2012

## **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 24, 2012

By: /s/ Lori Freedman

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

Secretary



## PSIVIDA CORP. REPORTS FOURTH QUARTER AND FISCAL YEAR 2012 RESULTS

WATERTOWN, MA – September 24, 2012 — 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 fourth quarter and fiscal year ended June 30, 2012.

"This has been another excellent quarter for us," said Dr. Paul Ashton, President and CEO. "The FDA recently cleared our IND for the posterior uveitis product we are independently developing, permitting us to move directly to two Phase III clinical trials with a 12 month primary end point of recurrence of uveitis and allowing us to reference much of the data, including the clinical safety data, from the clinical trials for ILUVIEN® for Diabetic Macular Edema (DME). We are currently planning the trials, which we expect will target enrollment of a total of 300 patients. Because we are using the same micro-insert used in ILUVIEN for DME, which delivers the same drug as our approved Retisert® product for posterior uveitis, we expect these trials will show efficacy with a comparable side-effect profile in uveitis patients as was seen in DME patients. As a result, we are optimistic that our micro-insert will be efficacious for posterior uveitis, with a favorable risk/benefit profile and fewer side effects compared to Retisert. At the end of June, we had over \$14 million in cash, cash equivalents and marketable securities and in August raised a further \$4.7 million from a registered direct offering of shares of common stock and warrants."

"We were also pleased with the progress on the commercialization of ILUVIEN for DME in the EU by our licensee Alimera Sciences. 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 DME considered insufficiently responsive to available therapies. Further, Alimera has reported its plan to launch ILUVIEN in Germany, the United Kingdom and France in 2013, and has announced a \$40 million equity financing, which Alimera believes upon closing will position it financially to proceed with that commercialization." continued Dr. Ashton. "Our collaboration agreement entitles us to receive 20% of net profits, as defined, on sales of ILUVIEN by Alimera in each of these countries."

The International Diabetes Federation estimates that approximately 19 million people in these 7 EU countries are currently living with diabetes, and Alimera estimates that approximately 1 million people living there suffer from DME.

With respect to U.S. regulatory matters, Alimera has reported that it met with the FDA in an effort to gain a better understanding of the regulatory path for ILUVIEN for DME. Alimera further reported that based upon this meeting, it plans to submit a response to the FDA's second complete response letter to include additional analysis of the benefits and risks of ILUVIEN based upon clinical data available from Alimera's completed FAME™ Study. 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 our bioerodilble, injectable latanoprost micro-insert for glaucoma and occular hypertension is ongoing," continued Dr. Ashton. pSivida granted Pfizer an exclusive option under various circumstances to license the development and commercialization worldwide of this micro-insert for human ophthalmic disease other than uveitis.

"We are encouraged by the progress of our pre-clinical programs. In July 2012, we announced the execution of our first funded technology evaluation agreement for our Tethadur<sup>TM</sup> protein/antibody delivery technology. The agreement, which is with a leading global biopharmaceutical company, covers the field of ophthalmology. Tethadur is an application of our BioSilicon<sup>TM</sup> technology platform designed to provide sustained delivery of large biologic molecules, including peptides, proteins and antibodies using an injectable, bioerodible, nanostructured, porous BioSilicon material for drug delivery. A sustained delivery system for these types of molecules which must currently be injected into the eye every one or two months would offer a significant clinical advance in the ophthalmic area."

Revenues for the fiscal year ended June 30, 2012 totaled \$3.5 million compared to \$5.0 million for the prior fiscal year. Revenues in both years included royalty income from sales of Retisert® by Bausch & Lomb and revenue recognition from the June 2011 amendment and restatement of the Pfizer collaboration agreement. In addition, fiscal 2012 reflected revenue recognition from the July 2011 termination of the Intrinsiq license agreement. For the year ended June 30, 2012, pSivida reported a net loss of \$24.8 million, or \$1.19 per share, compared to a net loss of \$8.6 million, or \$0.44 per share, for the prior fiscal year. Fiscal year 2012 results included a \$14.8 million impairment charge for pSivida's finite-lived intangible assets arising from the November 2011 complete response letter for ILUVIEN for DME and the resulting significant decrease in pSivida's share price.

Revenues for the fiscal 2012 fourth quarter were \$699,000 compared to \$3.7 million for the fourth quarter a year earlier. The fiscal 2011 fourth quarter included \$3.3 million of revenue recognition from the amended Pfizer collaboration agreement. pSivida reported a net loss of \$2.3 million, or \$0.11 per share, for the fourth quarter ended June 30, 2012, compared to a net loss of \$140,000, or \$0.01 per share, for the fourth quarter of the prior year.

At June 30, 2012, cash, cash equivalents and marketable securities totaled \$14.6 million. In August 2012, the Company completed a registered direct offering of shares of common stock and warrants raising net proceeds of \$4.7 million.

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

pSivida Corp. will host a live webcast and conference call today, September 24, 2012, at 4:30 pm ET. The conference call may be accessed by dialing (877) 303-6316 from the U.S. and Canada, or (650) 521-5176 from international locations. The conference can also be accessed on the pSivida Corp. website at <a href="https://www.psivida.com">www.psivida.com</a>. A replay of the call will be available approximately two hours following the end of the call through October 1, 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 32250064.

#### 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 Diabetic Macular Edema (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. The United States Food and Drug Administration (FDA) has cleared pSivida's Investigational New Drug application (IND) to treat posterior uveitis with the same micro-insert. 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: uncertainty as to the efficacy, risk/benefit profile and side effects of the posterior uveitis product candidate; uncertainties with respect to Alimera's ability to commercialize ILUVIEN for DME in the EU; no assurance that Alimera will resubmit its application or be able to demonstrate to the FDA that the benefits outweigh the risks of ILUVIEN for DME using data from their two previously completed pivotal Phase III clinical trials (FAME<sup>TM</sup> Study), that additional clinical trials will not be required, that the population of chronic DME patients will be acceptable to the FDA or that Alimera will be able to obtain regulatory approval for ILUVIEN for DME in the U.S.; ability of Alimera to consummate its pending financing; the timing and conditions for additional regulatory approvals are subject to decisions by regulators; necessity to raise additional capital to fully finance Phase III posterior uveitis trials as well as other working capital needs; ability to obtain additional capital; ability to initiate and complete clinical trials and obtain regulatory approval of product candidates; adverse side effects; Alimera's ability to successfully obtain regulatory approval of and commercialize ILUVIEN for DME in the EU; actions with respect to regulatory approval of ILUVIEN for DME in the EU; actions with respect to pre-clinical products using Tethadur and BioSilicon; further impairment of intangible assets; fluctuations in opera

competition; market acceptance of products and product candidates; reduction in use of products as a result of future guidelines, recommendations or studies; ability to protect intellectual property and avoid 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; 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.

## Released by:

**US Public Relations** 

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

(In thousands except per share amounts)

|   |                   | Three Months Ended<br>June 30, |                   | Year Ended June 30, |  |
|---|-------------------|--------------------------------|-------------------|---------------------|--|
|   | 2012              | 2011                           | 2012              | 2011                |  |
| Revenues:                                   |                   |                                |                   |                     |  |
| Collaborative research and development      | \$ 257            | \$ 3,394                       | \$ 2,080          | \$ 3,612            |  |
| Royalty income                              | 442               | 321                            | 1,446             | 1,353               |  |
| Total revenues                              | 699               | 3,715                          | 3,526             | 4,965               |  |
| Operating expenses:                         |                   |                                |                   |                     |  |
| Research and development                    | 1,410             | 1,851                          | 7,039             | 6,864               |  |
| General and administrative                  | 1,599             | 2,172                          | 6,868             | 8,104               |  |
| Impairment of intangible assets             | <u></u>           |                                | 14,830            |                     |  |
| Total operating expenses                    | 3,009             | 4,023                          | 28,737            | 14,968              |  |
| Operating loss                              | (2,310)           | (308)                          | (25,211)          | (10,003)            |  |
| Other income (expense):                     |                   |                                |                   |                     |  |
| Change in fair value of derivatives         | <del>_</del>      | 10                             | 170               | 1,140               |  |
| Interest income                             | 8                 | 11                             | 38                | 30                  |  |
| Other expense, net                          | <del>_</del>      | (2)                            | (1)               | (13)                |  |
| Total other income                          | 8                 | 19                             | 207               | 1,157               |  |
| Loss before income taxes                    | (2,302)           | (289)                          | (25,004)          | (8,846)             |  |
| Income tax benefit                          | 40                | 149                            | 169               | 218                 |  |
| Net loss                                    | <u>\$ (2,262)</u> | <u>\$ (140)</u>                | <u>\$(24,835)</u> | \$ (8,628)          |  |
| Net loss per share:                         |                   |                                |                   |                     |  |
| Basic and diluted                           | <u>\$ (0.11)</u>  | <u>\$ (0.01)</u>               | <u>\$ (1.19)</u>  | <u>\$ (0.44)</u>    |  |
| Weighted average common shares outstanding: |                   |                                |                   |                     |  |
| Basic and diluted                           | 20,803            | 20,745                         | 20,791            | 19,489              |  |

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

|  | June 30,<br>2012 | June 30,<br>2011 |
|--|------------------|------------------|
| Assets   |                  |                  |
| Current assets:                                  |                  |                  |
| Cash, cash equivalents and marketable securities | \$ 14,571        | \$ 24,128        |
| Other current assets                             | 1,388            | 1,238            |
| Total current assets                             | 15,959           | 25,366           |
| Intangible assets, net                           | 4,226            | 21,564           |
| Other assets                                     | 412              | 183              |
| Total assets                                     | <u>\$ 20,597</u> | \$ 47,113        |
| Liabilities and stockholders' equity             |                  |                  |
| Current liabilities:                             |                  |                  |
| Accounts payable and accrued expenses            | \$ 1,002         | \$ 1,650         |
| Deferred revenue                                 | 2,176            | 3,212            |
| Derivative liabilities                           |                  | 170              |
| Total current liabilities                        | 3,178            | 5,032            |
| Deferred revenue                                 | 3,783            | 4,635            |
| Deferred tax liabilities                         |                  | 13               |
| Total liabilities                                | 6,961            | 9,680            |
| Stockholders' equity:                            |                  |                  |
| Capital  | 264,452          | 262,927          |
| Accumulated deficit                              | (251,758)        | (226,923)        |
| Accumulated other comprehensive income           | 942              | 1,429            |
| Total stockholders' equity                       |                  | 37,433           |
| Total liabilities and stockholders' equity       |                  | \$ 47,113        |