# 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) July 31, 2008

# **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 simultaneous 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))

Dere-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 July 31, 2008, pSivida Corp. issued a press release announcing its quarterly highlights. A copy of the press release is furnished as Exhibit 99.1 hereto.

# Item 9.01 Financial Statements and Exhibits

# (d) <u>Exhibits</u>.

# No. Description

99.1 Press release of pSivida Corp. dated July 31, 2008

The information contained in this report (including Items 2.02 and 9.01) and the exhibits hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

# 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: August 5, 2008

By: <u>/s/ Michael J. Soja</u>

Michael J. Soja, Vice President, Finance and CFO



July 31, 2008

#### **ASX/Media RELEASE**

# pSivida Quarterly Highlights

Reincorporation in the US Completed
Interim results from Medidur for DME Study
Commencement of new Medidur AMD Trial
Commencement of BrachySil Pancreatic Cancer Dose Ranging Clinical Trial

Boston, MA. and Perth, Australia (July 31, 2008) –pSivida Corp. (NASDAQ: PSDV, ASX: PVA, FF: PSI) – a leading drug delivery company, headquartered in Watertown MA announced its Quarterly highlights.

#### **Cash Flow**

The cash balance at June 30, 2008 was US\$15.6m, a decrease of US\$2.6m from the balance at March 31, 2008. During the current quarter ended June 30, 2008, cash flows used in operating activities was US\$2.4m compared to cash flows provided by operating activities of US\$8.5m in the previous quarter ended March 31, 2008. Cash flows from operating activities in the current quarter included cash inflows from customers of US\$1.5m consisting primarily of US\$1.0m of research and development funding from Pfizer and US\$437k in connection with the amended collaboration agreement with Alimera Sciences. This compares to cash inflows from customers of US\$13.0m in the previous quarter, US\$12.0m of which was received from Alimera Sciences at the closing of the amended collaboration agreement that provides total consideration up to US\$78m plus a 20% share of future profits. Cash flows used in operating activities included US\$3.9m of outflows for the current quarter compared to US\$4.6m for the previous quarter.

Subsequent to June 30, 2008, Bausch and Lomb will retain the next US\$2.8m of Retisert<sup>®</sup> royalties otherwise payable to pSivida in accordance with an advance royalty agreement the Company entered into in June 2005. Royalties otherwise payable to pSivida for the quarter ended June 30, 2008 were US\$427k which represents a 15% increase from US\$371k for the quarter ended March 31, 2008 and a 24% decrease from US\$559k for the quarter ended June 30, 2007. Retisert<sup>®</sup> is the only FDA-approved treatment for posterior uveitis, a chronic eye disease.

### **Reincorporation in the US**

In June, the Company completed reincorporation in the United States following approval by shareholders. The reincorporation is designed to make the Company a more attractive investment for shareholders by increasing the potential scope and depth of the Company's shareholder base and liquidity, reducing ongoing compliance costs and enabling the Company to continue the engagement of its independent auditor, while maintaining strong ties with the Australian investor base. This move to the US was the next key step in the Company's long-standing strategy of building a global drug delivery company by focusing growth and development in the US where the company has achieved its recent significant business successes.

As a US company with common stock traded on NASDAQ, the Company files quarterly unaudited financial statements on Form 10-Q and full year financial statements on Form 10-K and will file these financial statements with ASX after they are filed with the US Securities and Exchange Commission.

### Interim Results from the three-month Human PK Medidur<sup>™</sup> FA Study

In June, the Company reported the interim three-month safety and efficacy results from the first human pharmacokinetic (PK) study of Medidur<sup>™</sup> FA, in patients with Diabetic Macular Edema (DME). This open-label Phase II study is designed to support the ongoing pivotal Phase III clinical trial of Medidur in DME by assessing systemic exposure to FA after administration of Medidur in the eye. The study is secondarily designed to provide information on the safety and efficacy of Medidur in a DME population.

A total of 37 subjects were enrolled in this trial, 20 patients on the low dose (an approximate 0.23µg per day dose) of Medidur and 17 patients on the high dose (an approximate 0.45µg per day dose) with the same inclusion/exclusion criteria as the ongoing Phase III study. The three month interim readout from the PK study indicated 20 percent of the low dose patients and 18 percent of the high dose patients showed an improvement in best-corrected visual acuity (BCVA) of 15 letters or greater from baseline on an eye chart. In addition, both the low dose and the high dose of Medidur resulted in a significant reduction in retinal thickness as compared to the baseline.

From a safety perspective, no adverse events related to intraocular, or inner eye, pressure were seen in the low dose patients, while 12 percent of the high dose patients experienced intraocular pressure increases of greater than 30 mmHg. Additionally, the only adverse event related to cataract formation was reported in a patient in the high dose group.

By comparison, the Retisert<sup>®</sup> intravitreal implant (FDA approved for Uveitis), which releases FA at an initial rate of 0.6 µg per day, was also studied in a DME population. Retisert data presented at the ARVO conference in 2004 and 2005 showed that at 6 months between 15% and 20% of DME patients receiving Retisert gained 15 letters from baseline on an eye chart and after 2 years this increased to 27% but there were some steroid related side effects, particularly cataract and elevation of IOP.

The early results of this study support our hypothesis that lower doses of FA delivered via the Medidur system will provide visual acuity improvements while reducing the risk of ocular side effects commonly associated with the use of corticosteroids.

The technology underlying Medidur FA for DME is licensed to Alimera Sciences, a privately funded biopharmaceutical company that specializes in the research, development and commercialization of prescription ophthalmic pharmaceuticals, in an agreement that provides total consideration of up to US\$78m plus a 20% share of future profits. Medidur FA for DME is in fully recruited Phase III clinical trials. If approved, it is anticipated that Medidur will be marketed under the name Iluvien<sup>TM</sup>.

#### Clinical trial to assess safety and efficacy of Medidur FA in patients with AMD treated with Lucentis®

In May, the Company announced that enrollment has begun for a clinical trial under an investigator sponsored IND to assess the safety and efficacy of Medidur<sup>TM</sup> FA in conjunction with Lucentis<sup>®</sup> (ranibizumab injection, Genentech) in patients with exudative age-related macular degeneration (wet AMD). The study is designed to provide preliminary information on the potential of Medidur FA to maintain the efficacy established with Lucentis while reducing the overall number of Lucentis treatments.

## Commencement of BrachySil Pancreatic Cancer dose ranging clinical trial

In July, the Company announced that a device dose ranging clinical trial commenced using BrachySil<sup>TM</sup> (P32 BioSilicon<sup>TM</sup>) as a potential new brachytherapy treatment for inoperable pancreatic cancer. The first patient received treatment at Guy's and St Thomas' NHS Foundation Trust in London. A total of six patients will be entered into this trial at two centers in the UK (Guy's and St Thomas' NHS Foundation Trust, and University Hospital, Birmingham). The study will determine the safety of escalating radiation doses of the BrachySil<sup>TM</sup> device, with tumor response as a secondary end point.

### **Opes Prime overhang cleared**

In April, the Company announced that all the Company's shares subject to Opes Prime margin lending facilities were sold in an orderly fashion after Opes Prime was placed in the hands of a receiver.

#### **New Board Appointments**

In July, the Company announced the appointment to the Board of Directors of Peter G. Savas and Paul A. Hopper as non-executive Directors. Both have demonstrated track records of success in building successful biotech companies and the pSivida Board will benefit from their skills and experience.

#### **Released by:**

pSivida Corp. Brian Leedman Vice President, Investor Relations pSivida Corp. Tel: +61 8 9227 8327 brianl@psivida.com US Public Relations Beverly Jedynak President Martin E. Janis & Company, Inc Tel: +1 (312) 943 1100 ext. 12 bjedynak@janispr.com

## About pSivida Corp.

pSivida is a leading drug delivery company committed to the biomedical sector and the development of drug delivery products. Retisert<sup>®</sup> is FDA approved for the treatment of AIDS-related CMV Retinitis. Bausch & Lomb owns the trademarks Vitrasert<sup>®</sup> and Retisert<sup>®</sup>. pSivida has licensed the technologies underlying both of these products to Bausch & Lomb. The technology underlying Medidur<sup>TM</sup> FA for diabetic macular edema is licensed to Alimera Sciences under an agreement with total consideration of up to US\$78m plus a 20% share of future profits and is in fully recruited Phase III clinical trials. If approved, it is anticipated that Medidur will be marketed under the name Iluvien. pSivida has a worldwide collaborative research and license agreement with previous and future payments of up US\$165m with Pfizer Inc. for certain other ophthalmic applications of the Medidur<sup>TM</sup> technology.

pSivida owns the rights to develop and commercialize a modified form of silicon (porosified or nano-structured silicon) known as BioSilicon<sup>™</sup>, which has applications in drug delivery, wound healing, orthopedics, and tissue engineering. The most advanced BioSilicon<sup>™</sup> product, BrachySil<sup>™</sup>, delivers a therapeutic, P32, directly to solid tumors and is presently in dose ranging clinical trials as a device for the treatment of pancreatic cancer.

pSivida's intellectual property portfolio consists of over 65 patent families, over 115 granted patents, including patents accepted for issuance and over 270 patent applications. pSivida conducts its operations from Boston in the United States, Malvern in the United Kingdom and Perth in Australia.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking and involve a number of risks and uncertainties. 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 forward-looking statements: achievement of milestones and other contingent contractual payment events; failure to prove efficacy for BrachySil; inability to raise capital; continued losses and lack of profitability; inability to develop or obtain regulatory approval for new products; inability to protect intellectual property or infringement of others' intellectual property; inability to obtain partners to develop and market products; termination of license agreements; competition; inability to pay any registration penalties; costs of international business operations; manufacturing problems; insufficient third-party reimbursement for products; failure to retain key personnel; product liability; inability to manage change; failure to comply with laws; failure to achieve and maintain effective internal control over financial reporting; amortization or impairment of intangibles; possible dilution through exercise of outstanding warrants and stock options or future stock issuances; potential restrictions from capital raises; possible influence by Pfizer; and other factors that may be 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. We do not undertake to publicly update or revise our forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied in such statements will not be realized.