# 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): May 3, 2011**

# PSIVIDA CORP.

**(Exact name of Registrant as specified in its charter)**

| **Delaware** | **000-51122** | **26-2774444** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(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)**

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 8.01. Other Events.**

On May 3, 2011, pSivida Corp. issued a press release announcing the presentation at the 2011 ARVO Annual Meeting of new data from the completed 36-month FAME™ Study of ILUVIEN® for the treatment of Diabetic Macular Edema (DME) sponsored by pSivida's licensee, Alimera Sciences, Inc. pSivida's press release and slides presented at the ARVO meeting are filed as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of pSivida Corp. dated May 3, 2011. |
| 99.2 | Slides of Andrew N. Antoszyk, MD presented May 3, 2011 at the 2011 ARVO Annual Meeting incorporated by reference to Exhibit 99.1 of Form 8-K of Alimera Sciences, Inc. furnished to the SEC on May 3, 2011. |

**SIGNATURES**

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.

By: /s/ LORI FREEDMAN

Name: Lori Freedman
Title: Vice President Corporate Affairs, General Counsel & Secretary

Dated: May 3, 2011

**FOR IMMEDIATE RELEASE**

**PSIVIDA ANNOUNCES NEW SAFETY AND EFFICACY DATA FROM PHASE 3 STUDY OF ILUVIEN® IN DIABETIC MACULAR EDEMA**

WATERTOWN, MA, May 03, 2011 (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 the presentation of new data from the completed 36-month FAME™ Study of ILUVIEN for the treatment of Diabetic Macular Edema (DME) at the 2011 ARVO Annual Meeting. The new data, presented by Dr. Andrew N. Antoszyk, analyzed the subgroup of patients who had been diagnosed with DME for three or more years at entry of the FAME Study (which comprises over 50% of patients in the Study). ILUVIEN is licensed by pSivida to Alimera Sciences, Inc. Alimera reported that it plans to submit this new subgroup data to the FDA in support of its pending New Drug Application.

In the data reported for this subgroup at 36 months in Trial A, 31.8% of patients treated with ILUVIEN experienced an improvement in best corrected visual acuity (BCVA) of 15 or more letters from baseline compared with 13.6% of those in the control group ($p=0.010$), for a net benefit of ILUVIEN versus control of 18.2%. In Trial B, 36.4% of ILUVIEN patients in this subgroup experienced improvement of 15 or more letters compared to 13.2% of control patients ($p= 0.004$), for a net benefit of ILUVIEN versus control of 23.2%. On a combined basis for both Trials A and B, at three years the net benefit of ILUVIEN compared to control reported for patients in the subgroup was 20.6%, more than double that seen for the full patient population (9.8%).

In the subgroup, peak efficacy was seen at month 30, with 33.6% of ILUVIEN treated patients in Trial A gaining 15 or more letters in BCVA compared to 10.2 % of control ($p < 0.001$) and 42.4% of ILUVIEN treated patients in Trial B gaining 15 or more letters in BCVA Trial B compared to 11.3% of control ($p< 0.001$).

Consistent with the full patient population in the FAME Study, approximately 75% of the patients in this subgroup treated with ILUVIEN were reported to have received only one ILUVIEN insert over the 36 month study.

There was no statistically significant difference in BCVA improvement in the subgroup of patients with less than three years' duration of DME at entry compared to control.

Safety data for patients within the subgroup of patients with DME diagnosis of at least 3 years' duration were also reported. Generally, subgroup patients receiving ILUVIEN experienced

fewer pressure-related side effects compared to control than was reported for the full patient population in the trial. By the end of the 36-month study, intraocular pressure (IOP) increases to 30 millimeters of mercury (mmHg) or greater at any time point were seen in 14.8% of the subgroup patients (5.4% of control), as contrasted with 18.4% of the full patient population (4.3% of control). By month 36, 5.3% of the subgroup patients had undergone an incisional surgical procedure to reduce elevated IOP (0.0% of control), compared to 4.8% in the full patient population (0.5% of control). During the study, 35.9% of the subgroup (15.2% of control) had received IOP-lowering medication compared to 38.4% of the full patient population (14.1% of control).

Data on cataracts for the subgroup were also reported. At the entry of the trial, many patients had already received cataract surgery. Of the remaining patients with a natural lens, the incidence of cataracts was 86.0% at month 36 for the subgroup (51.5% for control), with 85.1% undergoing a cataract operation (36.4% for control). By comparison, in the phakic full study patient population, the incidence of cataracts was 81.7% at month 36 (50.4% for control), with 74.9% undergoing a cataract operation (27.3% for control).

The FAME Study consisted of two three-year, Phase 3 pivotal clinical trials (Trial A and Trial B) to assess the safety and efficacy of ILUVIEN® in the treatment of DME. The 956 patients in the trials were randomized to receive either high dose ILUVIEN, low dose ILUVIEN or control treatment. The primary endpoint for efficacy in the trials was the difference in the percentage of patients whose BCVA improved by 15 or more letters from baseline on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart at month 24 between the treatment and control groups.

As previously reported, the pre-specified 24-month primary endpoint for the FAME Study was met for the low dose ILUVIEN in both Trial A and Trial B. Based on these data, Alimera submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) on June 29, 2010 for approval of the low dose ILUVIEN. Therefore, only the low dose data is presented and discussed in this press release. As previously reported, Alimera received a Complete Response Letter from the FDA in December 2010, requesting analyses of safety and efficacy data through month 36 of the FAME Study, including exploratory analyses in addition to those previously submitted in the NDA, to further assess the relative benefits and risks of ILUVIEN.

In February 2011, Alimera reported results from the full patient population at month 36 of the FAME Study.

Paul Ashton, President and Chief Executive Officer, said, “We are very pleased with the efficacy and safety results through month 36 in patients with chronic DME. This subgroup comprised a majority of patients in the FAME Study. We look forward to Alimera’s filing of this data with the FDA in connection with the NDA for ILUVIEN.”

Data for the subgroup analyses was gathered from 536 patients who had been diagnosed with DME for three years or more and 416 patients who had been diagnosed with DME for less than three years.

**About the FAME Study**

Alimera conducted two 36-month, Phase 3 pivotal clinical trials (collectively known as the FAME Study) for ILUVIEN involving 956 patients in sites across the United States, Canada, Europe and India to assess the efficacy and safety of ILUVIEN with two doses of the corticosteroid fluocinolone acetonide (FAc), a high and low dose, for the treatment of DME. The primary efficacy endpoint for the FAME Study was the difference in the percentage of patients whose best corrected visual acuity improved by 15 or more letters from baseline on the ETDRS eye chart at month 24 between the treatment and control groups. The study concluded in September 2010 with the final patient visit at the three-year data point.

**About DME**

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition is called DME. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a 10-year period approximately 19% of people with diabetes studied were diagnosed with DME. As the population of people with diabetes increases, Alimera expects the annual incidence of diagnosed DME to increase, as well.

**About ILUVIEN®**

ILUVIEN is an investigational, extended release intravitreal insert for the treatment of DME. Each ILUVIEN insert is designed to provide a therapeutic effect of up to 36 months by delivering sustained sub-microgram levels of FAc. ILUVIEN is inserted in the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. The insertion device employs a 25-gauge needle, which allows for a self-sealing wound.

**About pSivida Corp.**

pSivida is a world leader in the development of tiny drug delivery products that are administered by implantation, injection or insertion and provide sustained release of drugs on a controlled and level basis for months or years. pSivida uses these systems to develop treatments for serious, unmet, medical needs. In addition to ILUVIEN, pSivida's most advanced product candidate, pSivida has two products approved by the FDA for sustained release delivery of drug to treat chronic back-of-the-eye diseases: Retisert(R) for the treatment of posterior uveitis and Vitrasert(R) for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. pSivida has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated. pSivida also has a worldwide collaborative research and license agreement with Pfizer Inc. under which Pfizer may develop additional ophthalmic products using certain of the Company's technologies.

pSivida's intellectual property portfolio consists of over 50 patent families, more than 100 granted patents, including patents accepted for issuance, and more than 150 patent applications. pSivida conducts its operations from Boston in the United States and Malvern in the United Kingdom.

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 uncertain; 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 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. 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.