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) August 31, 2007





(Exact name of registrant as specified in its charter)

Western Australia, Commonwealth of Australia (State or other jurisdiction of incorporation) 000-51122 (Commission File Number)

Level 12 BGC Centre 28 The Esplanade Perth WA 6000 Australia

400 Pleasant Street Watertown, MA 02472 U.S.A. (Address of principal executive offices)

Registrant's telephone number, including area code (617) 926-5000

(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 (see General Instruction A.2. below):

□ 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 13e04(c) under the Exchange Act (17 CFR 240.13e-4(c))

Not applicable (IRS Employer Identification No.)

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
99.1	ASX Release: pSivida FAME Enrollment Complete

The information contained in this report (including Item 9.01) and the exhibit 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.

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 LIMITED

By: /s/ Michael J. Soja

Name: Michael J. Soja

Title: Vice President, Finance and Chief Financial Officer

Date: October 9, 2007

exhibit number 99.1 EXHIBIT DESCRIPTION

ASX Release: pSivida FAME Enrollment Complete

Exhibit 99.1



ASX/Media RELEASE

Lisa Lake Fleishman-Hillard for Alimera Sciences +1 404-739-0152 <u>lisa.lake@fleishman.com</u> **⊮ pSivida**

8 October 2007

Brian Leedman Vice President, Investor Relations pSivida Limited +61 8 9226 5099 <u>brianl@psivida.com</u>

ENROLLMENT COMPLETE IN PIVOTAL PHASE III TRIAL OF MEDIDUR™ FA FOR DIABETIC MACULAR EDEMA

ATLANTA, October 8, 2007 – Alimera Sciences Inc., a privately held ophthalmic pharmaceutical company, and pSivida Limited (NASDAQ:PSDV, ASX:PSD, Xetra:PSI), announced today that enrollment is complete for the FAMETM (<u>Fluocinolone Acetonide in Diabetic Macular Edema</u>) Study of MedidurTM FA for the treatment of Diabetic Macular Edema. FAME is a double masked, randomized, multi-center study that is following over 900 patients in the U.S., Canada, Europe, and India, for 36 months with safety and efficacy assessed at two years. Alimera Sciences and pSivida are jointly developing Medidur FA under a collaborative research and development agreement.

"Alimera Sciences is very excited to have completed enrollment in the FAME Study as this brings us closer to taking Medidur FA, the next generation of retinal drug delivery, to market and to our ultimate goal of delivering treatments that enrich patients' quality of life," said Alimera CEO Dan Myers.

Medidur, a tiny, injectable insert, is being studied as a way to deliver fluocinolone acetonide, a corticosteroid, to the retina for up to three years as a treatment for diabetic macular edema (DME). Using a proprietary 25 gauge injector system, an eye care professional injects the Medidur insert into the vitreous through a minimally invasive procedure in an outpatient setting.

"This marks an important milestone for the Company in our profit sharing collaboration with Alimera. We are very pleased at the continued development of Medidur FA, based on our technologies that have already been approved for two back of the eye diseases. We are optimistic that Medidur FA will offer a solution to the large market we see for this product," said pSivida Limited Managing Director, Dr Paul Ashton.

Diabetic retinopathy (DR), a complication of diabetes mellitus, is the leading cause of blindness in the working-age population of developed countries. At any time during progression of diabetic retinopathy, patients can develop DME which involves retinal thickening of the macular area. More than 500,000 people live with DME in the United States and this number is expected to exceed 700,000 by the year 2010. Currently there are no FDA approved drug treatments for DME.

About Alimera Sciences Inc.

Alimera Sciences Inc., an Atlanta, GA. based venture backed company, specializes in the development and commercialization of prescription ophthalmology pharmaceuticals. Founded by an executive team with extensive development and revenue growth expertise, Alimera Sciences products are focused on improving the delivery of therapeutic agents to enhance patients' lives and strengthen physicians' ability to manage ocular conditions. Alimera is currently conducting a phase III clinical trial of fluocinolone acetonide in the MedidurTM drug delivery system for the treatment of diabetic macular edema. For more information, please visit <u>www.alimerasciences.com</u>

About pSivida Limited

pSivida, a Boston, MA. based global drug delivery company, is committed to the biomedical sector. Retisert[®] is FDA approved for the treatment of uveitis. Vitrasert[®] is FDA approved for the treatment of AIDS-related CMV Retinitis. Bausch & Lomb own the trademarks Vitrasert[®] and Retisert[®]. pSivida has licensed the technologies underlying both of these products to Bausch & Lomb. The technology underlying Medidur[™] for diabetic macular edema is licensed to Alimera Sciences and is in Phase III clinical trials. pSivida has a worldwide collaborative research and license agreement with Pfizer Inc. for other ophthalmic applications of the Durasert[™] technology which underpins the Medidur product.

pSivida owns the rights to develop and commercialize a modified form of silicon (porosified or nano-structured silicon) known as BioSiliconTM, which has applications in drug delivery, wound healing, orthopedics, and tissue engineering. The most advanced BioSiliconTM product, BrachySilTM delivers a therapeutic, P32 directly to solid tumors and is presently in Phase II clinical trials for the treatment of pancreatic cancer. For more information, please visit <u>www.psivida.com</u>

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: the risks that we will not be able to raise additional capital; that we will continue to incur losses and may never become profitable; that we will be required to pay penalties pursuant to registration agreements with securities holders and not have sufficient funds to do so; that we will be unable to develop new products; that we will be unable to protect our own intellectual property or will infringe on others' intellectual property; that we will not receive regulatory approvals necessary to commercialize products; that we will be unable to secure partners necessary to develop and market products; that our current licensees will terminate their agreements with us; that our competitors' products will receive regulatory approval before, reach the market before, or otherwise receive better market acceptance than, our product candidates; that our international business operations will result in increased costs or delays; that manufacturing problems will delay product development and commercialization; that third-party reimbursement and health care providers will not cover the costs of our products; that we will fail to retain some or all of our key personnel; we will be subject to product liability suits and not have sufficient insurance to cover damages; that we will fail to effectively manage changes in our business; that we will fail to comply with environmental laws and regulations; that we will fail to achieve and maintain effective internal control over financial reporting; that amortization or impairment of other intangibles will adversely affect our operating results; that our being headquartered outside of the United States will make it difficult to effect legal services against us or our management, lead to adverse shareholder tax consequences, or otherwise limit shareholder rights; that we will be delisted from the ASX or NASDAQ; that our expectation to not pay cash dividends will decrease our stock price; that exercise of outstanding warrants and stock options will dilute ownership and reduce stock price; that future stock issuances could dilute ownership, restrict operations, encumber assets, or otherwise cause a decline in stock price; and the risk that Pfizer will influence our business in non-beneficial ways; 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