

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 6-K**

REPORT OF FOREIGN ISSUER  
Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934  
**For the month of June 2006**

Commission File Number 000-51122

**pSivida Limited**

(Translation of registrant's name into English)

Level 12 BGC Centre  
28 The Esplanade  
Perth WA 6000

(Address of principal executive offices)

(Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F).

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82- \_\_\_\_.

**SIGNATURE**

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

Date: June 7, 2006

pSivida Limited

By: /s/ Aaron Finlay

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Aaron Finlay  
Company Secretary

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**EXHIBIT INDEX**

**EXHIBIT 99.1:** Medidur™ Diabetic Macular Edema Programme: Government Approvals for International Clinical Phase III Trials



ASX/MEDIA RELEASE

7 June 2006

## **Medidur™ Diabetic Macular Edema Programme: Government Approvals for International Clinical Phase III Trials** Studies to begin in UK, Canada and India

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Boston, MA., Perth, Australia and Atlanta GA – Global bio-nanotech company pSivida Limited (ASX:PSD, NASDAQ:PSDV, Xetra:PSI) and development partner Alimera Sciences Inc., are pleased to announce that regulatory agencies in the U.K., Canada and India have approved the commencement of Phase III clinical trials of the Medidur™ device for the treatment of diabetic macular edema (DME). These international clinical sites are opening in conjunction with the sites already underway in the U.S. The Medidur development plan has already been granted Fast Track status in the U.S. by the Food and Drug Administration (FDA).

Medidur, a tiny injectable device, delivers the steroid fluocinolone acetonide (FA) directly to the back of the eye and is designed to treat DME. DME is a common, blinding eye disease, and is a leading cause of vision loss in people below 65 years of age worldwide. It affects approximately 10% of diabetics, with over 500,000 people in the U.S. and millions world-wide having the disease. Presently there are no FDA approved drug treatments for DME and the standard of care consists of laser surgery that is often ineffective and, at best, generally provides temporary relief of symptoms.

Sustained delivery of FA to the back of the eye has previously been shown to reduce edema in patients with DME, reduce the progression of their diabetic retinopathy, and most importantly, at three years provide a clinically significant increase in many patients vision\*. These results were generated in a 198 patient clinical trial conducted in the U.S. with the Retisert™ product by pSivida partner, Bausch & Lomb. Retisert, a surgically implanted device, delivers FA to the back of the eye. It has been approved by the FDA for the treatment of uveitis, a leading cause of blindness in the U.S.

"Medidur is a simple injectable device that does not require surgery. We hope the Phase III studies with the Medidur device will show similar efficacy to previous trials with sustained release FA," said Gavin Rezos CEO of pSivida. "We believe the initiation of the international phase of the studies is an important milestone which will both accelerate recruitment and enable physicians, patients, and regulatory authorities in different countries to gain experience with the product before approval is sought."

According to Dan Myers, CEO of Alimera Sciences Inc., "We believe that the initiation of international clinical sites is a great achievement and a significant step for our two companies."

**-ENDS-**

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**pSivida Limited**  
Brian Leedman  
Investor Relations  
pSivida Limited  
Tel: + 61 8 9226 5099  
brianl@psivida.com

**US Public Relations**  
Beverly Jedynek  
President  
Martin E. Janis & Company, Inc  
Tel: +1 (312) 943 1100 ext. 12  
bjedynek@janispr.com

#### **NOTES TO EDITORS:**

\*Three year follow-up data from a clinical trial of sustained release Fluocinolone acetonide (FA) in 198 patients with DME was presented at the annual ARVO conference in May 2006. At 3 years more patients receiving sustained release FA had an improvement in vision of 3 lines compared with those receiving standard of care (laser). This was statistically significant ( $p < 0.05$ ). Also at 3 years, more patients receiving FA had a complete resolution of their edema compared with those receiving laser ( $p < 0.05$ ). At 2 years (the last time point for which a complete data set exists) more patients receiving FA also had stable or improved diabetic retinopathy compared with those receiving laser ( $p < 0.05$ ).

#### **About pSivida Limited**

pSivida is a global bio-nanotech company committed to the biomedical sector and the development of drug delivery products. 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™, a treatment for diabetic macular edema, is licensed to Alimera Sciences and is in Phase III clinical trials.

pSivida owns the rights to develop and commercialise a modified form of silicon (porosified or nano-structured silicon) known as BioSilicon™, which has applications in drug delivery, wound healing, orthopaedics, and tissue engineering. pSivida's subsidiary, AION Diagnostics Limited is developing diagnostic products and the subsidiary pSiNutria is developing food technology products both using BioSilicon™.

pSivida's intellectual property portfolio consists of 70 patent families, 74 granted patents and over 290 patent applications. pSivida conducts its operations from offices and facilities near Boston in the United States, Malvern in the United Kingdom, Perth in Australia and Singapore.

pSivida is listed on NASDAQ (PSDV), the Australian Stock Exchange (PSD) and on the Frankfurt Stock Exchange on the XETRA system (German Symbol: PSI. Securities Code (WKN) 358705). pSivida is a founding member of the NASDAQ Health Care Index and the Merrill Lynch Nanotechnology Index.

The Company's largest shareholder and a strategic partner is QinetiQ, a leading international defence, security and technology company, formed in 2001 from the UK Government's Defence Evaluation & Research Agency (DERA). QinetiQ (QQ.) was instrumental in discovering BioSilicon™ and pSivida enjoys a strong relationship with, including access to its cutting edge research and development facilities.

For more information, visit [www.psivida.com](http://www.psivida.com)

#### **About Alimera Sciences Inc.**

Alimera Sciences Inc. specializes in the development and commercialization of over-the-counter and prescription ophthalmology pharmaceuticals. Founded by an executive team with extensive development and revenue growth expertise, Alimera Sciences' products address both the anterior (front) and posterior (back) segments of the eye, as well as underserved and overlooked areas of the ophthalmic market. The company is headquartered in Alpharetta, Georgia.

[www.alimerasciences.com](http://www.alimerasciences.com)

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This document contains forward-looking statements that involve risks and uncertainties. The statements are indicated by the use of words such as "believes", "expects", "anticipates" and similar words and phrases. Although we believe that the expectations reflected in such forward-looking statements are reasonable at this time, we can give no assurance that such expectations will prove to be correct. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Actual results could differ materially from those anticipated in these forward-looking statements due to many important factors including: failure to complete negotiations for new

centers for the BrachySil™ phase IIb clinical trial for inoperable primary liver cancer; failure of our discussions with the FDA for BrachySil™ to continue or to lead to FDA approval; failure of the BrachySil™ phase IIb clinical trial for inoperable primary liver cancer to determine the optimal dose, provide key safety data or support future pivotal efficacy trials or product registration or approval; failure of the BrachySil™ primary liver programme that is in phase IIb clinical trials to provide a valuable platform for the development and commercialisation of BrachySil™ for pancreatic cancer and other indications; failure to commence phase IIa BrachySil™ trials for the treatment of pancreatic cancer; failure of the findings of the pancreatic cancer phase IIa trial to provide a platform for further multicentre efficacy and safety trials; failure of there to be optimisation and standardisation between the two pancreatic cancer study centres; failure of the results of the Retisert™ for DME trial to be a good indicator of the results of pSivida's ongoing phase III Medidur™ for DME trial; failure of the Medidur™ trials in DME to show a very similar improvement in visual acuity and diabetic retinopathy severity score as Retisert™ for DME; failure of Medidur™ to release fluocinolone acetonide at the same rate as Retisert™; our inability to recruit patients for the phase III Medidur™ for DME trial; failure to develop applications for BioSilicon™ due to regulatory, scientific or other issues; our inability to successfully integrate Control Delivery Systems, Inc.'s operations and employees; failure of the pSivida Inc's products to achieve expected revenues; our inability to develop existing or proposed products; failure of the Bausch & Lomb/Novartis co-promotion arrangement to provide faster royalty growth; failure of our evaluation agreements to result in license agreements; failure to achieve cost savings generally; and failure to execute on U.S. growth strategy. Other reasons are contained in cautionary statements in the Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission, including, without limitation, under Item 3.D, "Risk Factors" therein. We do not undertake to update any oral or written forward-looking statements that may be made by or on behalf of pSivida.

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