

**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 February 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: February 21, 2006

pSivida Limited

By: /s/ Aaron Finlay

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Aaron Finlay  
Chief Financial Officer and Company Secretary

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**EXHIBIT INDEX**

- EXHIBIT 99.1:** Uveitis long term trial results positive
- EXHIBIT 99.2:** Diabetic Macular Edema trial with Retisert

## **pSivida: Uveitis long term trial results positive for pSivida**

*Second set of follow-up trial results announced today*

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Global bio-nanotech company pSivida Limited (**NASDAQ:PSDV, ASX:PSD, Xetra:PSI**) today announced that preliminary three year follow-up data from Bausch and Lomb's multi-center, randomized, dose-masked clinical trial of Retisert™ for the treatment of chronic non-infectious posterior segment uveitis has been published. Global eye health company, Bausch and Lomb (NYSE: BOL), exclusive licensee of Retisert™, conducted the study that showed the recurrence rate was significantly lower in eyes receiving Retisert™ than in non-implanted eyes. This study involved 278 patients from 27 hospitals in the United States and one in Singapore.

pSivida receives royalties from sales of Retisert™ which is presently priced at US\$18,250. Covered in the United States by Medicare and Medicaid, Retisert™ is co-marketed in the United States by Bausch & Lomb and Novartis.



*Surgically implantable Retisert™*

Posterior uveitis is the third leading cause of blindness in the United States where it afflicts an estimated 175,000 people. Approximately 800,000 people have the disease worldwide. Uveitis is a chronic auto-immune disease in which the body's own defences attack the inner lining of the eye (the uvea). Retisert™, approved by the FDA in April 2005, is the only FDA approved drug for this disease. Retisert™ is surgically implanted into the eye and is approved to release a constant amount of the drug, fluocinolone acetonide, over a treatment period of 30 months.

The study concluded that at three years control of uveitis in eyes implanted with Retisert™ was still significantly better than in non-implanted eyes, but was less effective than at two years and that some eyes may need to be re-implanted between 24 and 36 months.

“These results confirm the long term benefits of Retisert™ in the treatment of this devastating disease,” said Mr Gavin Rezos, CEO of pSivida Limited. “The possible need for an additional implant at between 24 and 36 months is consistent with the 30 month label from the FDA”.

In this study, patients were randomised to receive either a 0.59 mg or a 2.1 mg Retisert™ device. Data presented was the aggregate of the two doses. At three years, the recurrence rate of uveitis was 33% in the eye receiving Retisert™ compared to 57% of fellow eyes ( $p < 0.001$ ). A greater number of eyes receiving Retisert™ experienced an improvement in vision of at least 15 letters (three lines on an eye chart) compared to fellow eyes (22% versus 6%,  $p < 0.001$ ). 45% of eyes receiving Retisert™ required an operation to relieve elevated intraocular pressure and 92% developed a cataract. Cataract surgery is a relatively uncomplicated and established procedure with a high success rate.

The abstract (#1523) detailing this data is available on the website of the Association for Research in Vision and Ophthalmology [www.arvo.org](http://www.arvo.org). Fuller data will be presented at the ARVO conference in May 2006.

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**pSivida Limited**

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

**US Public Relations**

Beverly Jedynak  
President  
Martin E. Janis & Company, Inc  
Tel: +1 (312) 943 1100 ext. 12  
bjedynak@janispr.com

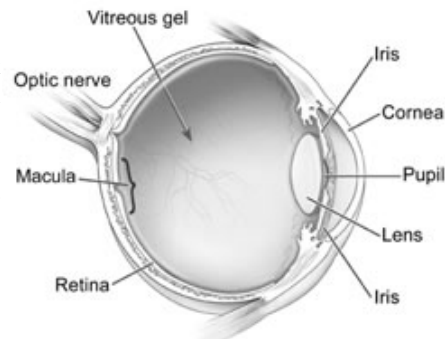
**UK & Europe Public Relations**

Mark Swallow / Helena Podd  
Citigate Dewe Rogerson  
Tel: +44 (0)20 7638 9571  
mark.swallow@citigatedr.co.uk

**NOTES TO EDITORS:**

**What is Uveitis?** An autoimmune condition, Uveitis manifests itself as an inflammation inside the eye, that can lead to sudden or gradual vision loss. It can be caused by diseases such as multiple sclerosis, rheumatoid arthritis

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. The technologies underlying both of these products are licensed to Bausch & Lomb.



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 Massachusetts, Malvern in the United Kingdom, Perth in Western Australia and Singapore.

pSivida is listed on NASDAQ (**PSDV**), the Australian Stock Exchange (**PSD**) and in Germany 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 July 2001 from the UK Government's Defence Evaluation & Research Agency (DERA). QinetiQ was instrumental in discovering BioSilicon™ and pSivida enjoys a strong relationship with it having access to its cutting edge research and development facilities. For more information visit [www.QinetiQ.com](http://www.QinetiQ.com)

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

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: our failure to develop applications for BioSilicon™ due to regulatory, scientific or other issues, our inability to successfully integrate CDS' operations and employees; the failure of the CDS' products to achieve expected revenues and the combined entity's inability to develop existing or proposed products; the failure of the Bausch & Lomb/Novartis co-promotion arrangement to provide faster royalty growth. Other reasons are contained in cautionary statements in the Registration Statement 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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## **pSivida: Diabetic Macular Edema trial with Retisert™**

### ***Positive Results for pSivida***

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Global bio-nanotech company pSivida Limited (NASDAQ:PSDV, ASX:PSD, Xetra:PSI) today announced the publication of preliminary three year follow-up data from Bausch and Lomb's multi-center, randomized, controlled clinical trial of Retisert™ for the treatment of diabetic macular edema (DME). Global eye health company, Bausch and Lomb (NYSE: BOL), exclusive licensee of Retisert™ from pSivida, conducted the study in hospitals in the United States in which 197 patients were randomised to receive either standard of care (repeat laser or observation) or a Retisert™ implant. The study concluded that significantly more patients receiving a Retisert™ implant had improved visual acuity (of three or more lines on an eye chart) than those receiving standard of care.

DME, a common complication of Diabetic Retinopathy (DR), is the leading cause of vision loss in people under the age of 65 in the United States with an estimated 500,000 treatable cases. DME is characterized by swelling of the retina and loss of vision. Currently the only FDA approved treatment is laser therapy in which holes are burned into the macula with a laser. This treatment is often ineffective or generally provides only temporary benefit. There are no approved drug therapies for the treatment of either DME or DR. Retisert™ for DME is surgically implanted into the eye and releases a constant amount of the drug, fluocinolone acetonide. Retisert™ is FDA approved for the treatment of posterior uveitis with a duration of 30 months and is licensed to Bausch & Lomb and co-promoted by Novartis.



*Injectable Medidur™*

Medidur™ is pSivida's next generation product. It is a tiny, injectable device that can release the same drug as Retisert™. Unlike Retisert™, which is surgically implanted, Medidur™ is injected into the eye during an office visit. Medidur™ is in Phase III clinical trials in DME in collaboration with Alimera Sciences Inc., a specialty pharmaceutical company focused on the ophthalmic industry.



*Surgically implantable Retisert™*

“As Retisert™ and Medidur™ can deliver the same drug, at a similar rate, to the back of the eye, we hope the Medidur™ trials in DME show a very similar improvement in visual acuity to that shown in the Retisert™ DME trial. Medidur™ differs from Retisert™ in that it is a smaller device that can be inserted without the need for surgery,” said Mr Gavin Rezos, CEO of pSivida Limited.

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Results of the Bausch & Lomb study has shown that a statistically significant number of eyes treated with Retisert™ had an improvement of visual acuity of three or more lines on an eye chart compared to eyes receiving standard of care (28% versus 15%, p<0.05). Additionally, a statistically significant number of eyes treated with Retisert™ showed an improvement in their diabetic retinopathy severity score, a measure of the severity of their disease (13% versus 4% p<0.001). More eyes receiving Retisert™ also showed a reduction in their edema and there was also no evidence of edema in 58% of eyes receiving the implant versus 30% of eyes receiving standard of care (p<0.001).

Side-effects of Retisert™ in patients with DME were similar to those reported in patients with uveitis for which Retisert™ is approved. Of the patients with DME receiving Retisert™, at three years 33% required an operation to relieve elevated intraocular pressure (IOP) and 95% required cataract surgery. Cataract surgery is a relatively uncomplicated and established procedure with a high success rate. The abstract (#5442) detailing the DME data is available on the website of the Association for Research in Vision and Ophthalmology [www.arvo.org](http://www.arvo.org). The three year uveitis data is available at the same website (abstract #1523). Fuller data will be presented at the ARVO conference in May 2006.

pSivida receives royalties from sales of Retisert™ for chronic non-infectious posterior segment uveitis, a sight threatening condition that affects an estimated 175,000 people in the United States and an estimated 800,000 people worldwide. The product is presently priced at US\$18,250 and is approved as a 30 month treatment. Covered in the United States by Medicare and Medicaid, Retisert™ is co-marketed in the United States by Bausch & Lomb and Novartis. In the event that Retisert™ is approved for DME and Bausch & Lomb decide to market Retisert™ for DME, then pSivida will receive royalty payments from Bausch & Lomb for Retisert™ sales for DME.

-ENDS-

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

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

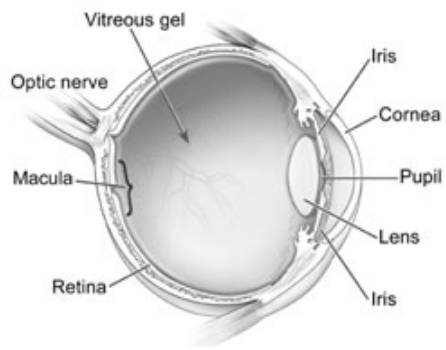
**UK & Europe Public Relations**  
Mark Swallow / Helena Podd  
Citigate Dewe Rogerson  
Tel: +44 (0)20 7638 9571  
mark.swallow@citigatedr.co.uk

**NOTES TO EDITORS:**

**What is Diabetic Retinopathy?** Diabetic Retinopathy is a complication of diabetes and a leading cause of blindness. It occurs when diabetes damages the tiny blood vessels inside the retina, the light-sensitive tissue at the back of the eye. A healthy retina is necessary for good vision. Diabetic Retinopathy usually affects both eyes.

**What is Diabetic Macular Edema?** Diabetic Macular Edema, a subset of diabetic retinopathy, is the leading cause of vision loss for Americans under the age of 65. Retinal blood vessels in diabetic's eyes deteriorate and leak, causing the retina to swell. A minority of cases receive long-term benefit from laser treatment.

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