

**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 2005**

**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 15, 2005

pSivida Limited

By: /s/ Aaron Finlay  
Aaron Finlay  
*Chief Financial Officer and Company Secretary*

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**EXHIBIT INDEX**

**EXHIBIT 99.1:** pSivida Limited Press Release, dated February 15, 2005 (Positive Phase IIa Trial Results in Liver Cancer)



FOR IMMEDIATE RELEASE

15<sup>th</sup> February 2005

## Positive Phase IIa Trial Results in Liver Cancer

*BrachySil™ trial confirms safety and tumor regression in further patients*

Global nanotechnology company pSivida Limited (NASDAQ:PSDV, ASX:PSD, Xetra:PSI) is pleased to announce that its trial in inoperable primary liver cancer patients continues to show excellent results. Data from the second patient cohort of the current Phase IIa trial has further demonstrated that BrachySil™ (32-P BioSilicon™) is safe and effective in tumor regression with increased efficacy.

Results of the second group of 4 patients, 12 weeks after their BrachySil™ treatment, revealed an average tumor regression by volume of 80% as determined by CT scanning. In some smaller tumors 100% regression was observed, a level of performance not seen with other intratumoral approaches. The study also demonstrated that there were no product-related adverse effects. Patients will continue to be monitored for 6 months post treatment.

These excellent results follow the announcement in October 2004 of the interim results from the first 4 patients, which also showed no product-related adverse effects and reported up to 60% regression of tumors.

BrachySil™ is a micron-sized particle in which the isotope 32-phosphorus is immobilized. pSivida believes that this product is unique in that it demonstrates a very high degree of isotope retention, thus reducing the risk of soluble radioactive material affecting healthy hepatic tissue or entering the circulation and causing systemic toxicity.

pSivida's Managing Director, Mr. Gavin Rezos, said, "This further human evaluation of BioSilicon™ has met our expectations in terms of safety and the performance of the fine gauge needle injection procedure. We are also very pleased with the significant level of tumor regression achieved given the low dose being administered. Proof of the ability of BrachySil™ to retain radioactivity at the injection site is another significant outcome of the trial."

Other treatments for primary liver cancer include a variety of embolisation and radiofrequency ablation techniques. pSivida believes that BrachySil™ potentially offers the interventional radiologist a more versatile and safer product for the treatment of such tumors. The procedure is undertaken without surgery under local anesthetic and patients can be discharged the following day.

pSivida currently plans to pursue a 'device-based' regulatory approval route for BrachySil™ which could result in a much shorter development and registration timeframe than that commonly associated with a drug-based approval.

Following the completion of analysis of the final Phase IIa trial results pSivida expects to begin a dose profiling study during 2005. pSivida then intends to commence multi-centre pivotal registration trials during 2005 involving patients in Asia, Europe and the US. The objective of these trials is to obtain data to support registration of BrachySil™ as an approved treatment for primary liver cancer.

pSivida plans to expand the use of BrachySil™ as a treatment for a wider range of solid tumor indications. A Phase IIa clinical trial is scheduled to commence for a second cancer indication within the next year.

The brachytherapy market is currently over US\$600 million per annum and is expected to exceed US\$1 billion within the next few years (Bio-Tech Systems). BrachySil™ has the potential to significantly expand the current market size through its application to other cancers.

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The study has established **four** key findings:

- ***SAFETY - No product related adverse events***

Unlike other liver brachytherapy approaches that involve delivery via the hepatic artery and, in some cases, result in radioactivity affecting healthy tissue, BrachySil™ is administered directly into tumors restricting radioactivity to the tumor itself.

- ***EFFICACY - Treated tumors demonstrate significant tumor regression***

Implantation of tumors with BrachySil™ has resulted in tumoricidal activity around the implantation site. Although the primary objective of the study was to determine the safety profile of BrachySil™, CT scan analysis of tumors at the time of treatment and 3 months later demonstrates significant tumor regression in targeted lesions with a maximum regression of 100% from the dose used in the trial.

- ***SPECIFICITY- Retention of radioactivity in the tumor***

A key finding is that the radioactive <sup>32</sup>P-BioSilicon™ nanostructured microparticles remain in the tumor with no or insignificant detectable radioactive leakage.

• **EASE OF APPLICATION - Practical and rapid treatment of tumors with ultrasound and CT guidance**

The procedure has been shown to be straightforward and accurate for the treatment of tumors. From a market perspective this demonstration is in line with the company's strategy to develop a simple procedure for the interventional radiologist to selectively treat specific tumors. A multi injector is in design phase to treat larger tumors with multiple implantations from a single entry.

**NOTES ON BRACHYSIL AND COMPETITIVE ADVANTAGES IN BRACHYTHERAPY**

1. BrachySil™ is being manufactured to worldwide regulatory guidelines by supply chain contract partners including HighForce, Micron Group, Atomising Systems and AEA Technology QSA subsidiary Auriga Medical, a leading global producer and supplier of radioisotopes for healthcare.
2. Brachytherapy treatment utilising BioSilicon™ includes the following significant potential advantages:
  - **Short range** - <sup>32</sup>P isotope has a short active range resulting in less damage to healthy tissue.
  - **Immobilization** - <sup>32</sup>P device is immobilized in the tumor, significantly reducing risk of leakage or systemic side effects.
  - **Ease of application** - BrachySil™ is delivered under local anesthetic and patients can be discharged the next day.
  - **Direct delivery** - BrachySil™ is delivered via fine gauge needle, minimizing side effects and tissue trauma without the need for shielded rooms or robotic injectors allowing treatment in hospitals without the need for investment in specialised facilities.
  - **Range of tumors** - fine gauge needle delivery allows potential application to many solid tumors, unlike current brachytherapy products.
  - **Distribution** - <sup>32</sup>P half-life of 14 days allows more convenient distribution to hospitals and application in the patient.
  - **Manufacture** - BioSilicon™ is radiation hard allowing ease of manufacture of BrachySil™ from phosphorous-doped silicon used in the electronics industry without the need to build costly manufacturing facilities.

**-ENDS**

**Released by:**

**In Australia:**

Josh Mann  
Investor Relations  
pSivida Limited  
Tel: + 61 8 9226 5099  
joshuamann@psivida.com

**In US:**

Beverly Jedynek  
President  
Martin E. Janis & Company, Inc.  
Tel: 312-943-1100 ext. 12  
bjedynek@janispr.com

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**NOTES TO EDITORS:****Ticker Symbols**

Australian Stock Exchange

:PSD

NASDAQ

:PSDV

Frankfurt Stock Exchange (Xetra)

:PSI

**pSivida Limited**

pSivida is a global nanotechnology company committed to the biomedical sector and the development of products in healthcare. The company's focus is the development and commercialisation of a modified form of silicon (porosified or nano-structured silicon) known as BioSilicon™. As a new and exciting biocompatible material, BioSilicon™ offers multiple potential applications across the

high growth healthcare sector, including controlled release drug delivery, targeted cancer therapies (including brachytherapy and localized chemotherapy), tissue engineering and orthopedics. Potential diagnostics applications are being developed through its subsidiary AION Diagnostics Limited.

pSivida owns the intellectual property rights to BioSilicon™ for use in or on humans and animals. The IP portfolio consists of 24 patent families, 26 granted patents and over 80 patent applications. The core patent, which recognises BioSilicon™ as a biomaterial was granted in the UK in 2000 and in the US in 2001.

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's shares also trade in the United Kingdom on the OFEX International Market Service (IMS) under the ticker symbol **PSD**.

The Company's strategic partner and largest shareholder is the QinetiQ group, the largest science and technology company in Europe. QinetiQ is the former UK government Defence Evaluation Research Agency and was instrumental in discovering BioSilicon™. pSivida enjoys a strong relationship with QinetiQ having access to its cutting edge research and development facilities. For more information on QinetiQ visit [www.qinetiq.com](http://www.qinetiq.com).

pSivida has a strong management team with a powerful blend of international experience in biotechnology commercialization, the pharmaceutical industry, licensing and capital markets:

- **Mr Gavin Rezos, Managing Director** - a former Investment Banking Director of the HSBC Group.
- **Dr Roger Brimblecombe, Non Executive Chairman** - former Chairman of SmithKline & French Research and Chairman of MVM Ventures.
- **Dr Roger Aston, Director Strategy** - former CEO PepTech Ltd and Director of Cambridge Antibody Technology Ltd (UK).
- **Professor Leigh Canham, Chief Scientific Officer** - a DERA fellow and the world's foremost authority on porous silicon and the inventor of BioSilicon™.
- **Dr Anna Kluczevska, Managing Director, AION Diagnostics** - a former Global Product Manager with Baxter Healthcare Inc, based in Munich and Vienna.

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

This document contains forward-looking statements that involve risks and uncertainties. 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. 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.