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 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 I Form 40-F o

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 o 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.

pSivida Limited

Date: June 21, 2005

By: /s/ Aaron Finlay

Aaron Finlay Chief Financial Officer and Company Secretary

EXHIBIT INDEX

EXHIBIT 99.1: BrachySil[™] Cancer Therapy Achieves Primary Endpoint in Phase IIa Clinical Trials



BrachySil[™] Cancer Therapy Achieves Primary Endpoint in Phase IIa Clinical Trials Final Report Confirms BrachySil[™] Safe and Well Tolerated

Global nanotechnology company pSivida Limited (ASX:PSD, NASDAQ:PSDV, XETRA:PSI) and the Singapore General Hospital ("SGH"), are very pleased to announce key findings from the final report on its Phase IIa clinical trials with BrachySilTM as a potential new brachytherapy treatment for inoperable primary liver cancer.

The report confirms that the primary endpoint of the trial was achieved in its key first indication in that BrachySilTM (32-P BioSiliconTM) was found to be both safe and well tolerated. The trial was conducted at the SGH on eight patients with advanced liver cancer who were evaluated after three and six months following treatment.

Among other key findings of the trial was the finding that BrachySilTM also reduced significantly the size of tumors treated as determined by CT scanning. These combined results pave the way for a multi-centre Phase IIb dose-profiling study for BrachySilTM in this indication, which is scheduled to begin later in 2005. This study is expected to provide data to support the registration of BrachySilTM as an approved treatment for liver cancer.

Gavin Rezos, Managing Director of pSivida, said, "This report confirms the excellent results for BrachySil[™] that we previously announced at the 12-week interim study time point, and will provide not only a robust foundation for future clinical development and regulatory filing, but also a springboard for our ongoing licensing activities with partners looking to enhance their own portfolios of specialist cancer therapies."

Dr Pierce Chow, Senior Consultant, Hepatobiliary and General Surgery at Singapore General Hospital, said, "From the perspective of patients suffering with advanced cancer of this kind, BrachySil[™] promises to offer the possibility of an effective, safe and relatively pain-free treatment, which can potentially improve both the duration and quality of life. We, at the SGH, are very encouraged by the promising data seen to date with BrachySil[™] and are optimistic that subsequent clinical trials will continue to show positive results in this and other serious cancer indications."

BrachySil[™] is a micron-sized nanostructured silicon particle in which radioactive 32-phosphorus (32-P) is immobilized. It is administered as a liquid suspension through a fine-gauge needle directly into tumors. The procedure takes place under local anaesthetic and without the need for shielded rooms or robotic injectors, and patients can be discharged the next day.

Key Findings

The final report of the Phase IIa clinical trial has confirmed **four** key findings:

· Safety - No product-related adverse events

BrachySil[™] was found to be well tolerated by all eight patients in the trial group. No significant product-related adverse events were reported either immediately following implantation or during the six month follow-up period. Adverse events tended to be mild and transient.

· Efficacy - Treated tumors demonstrate significant tumor regression

Implanting BrachySilTM directly into tumors results in significant tumoricidal activity. Although the primary objective of the study was to determine the safety profile of BrachySilTM, CT scan analysis of tumors at the time of treatment and three and six months later demonstrates significant tumor regression in targeted lesions with a maximum regression of 100% in some small tumors from the dose used in the trial.

· Specificity - Retention of radioactivity in the tumor

A key finding is that BrachySilTM microparticles remain in the tumor with no or insignificant detectable radioactive leakage. This observation is a very significant outcome for the trial. Unlike other liver brachytherapy approaches that involve delivery via the hepatic artery which, in some cases, results in radioactivity becoming associated with healthy tissue, BrachySilTM is administered directly into tumors restricting radioactivity to the tumor itself.

· 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 in a routine and conventional clinical setting. From a market perspective, this demonstration is in line with the Company's strategy to develop a simple procedure for the nuclear medicine physician and interventional radiologist to selectively treat specific tumors.

Next Steps

As mentioned above, pSivida is planning to initiate a multi-centre Phase IIb dose-profiling study for BrachySilTM as a treatment for advanced liver cancer in the second half of 2005.

The Company plans to pursue a 'device-based' regulatory strategy, with BrachySil[™] filings scheduled in 2007 initially as a treatment for liver cancer and thereafter for the treatment for other cancers involving solid tumors.

pSivida has already started a development programme for BrachySil[™] in a second key cancer indication - pancreatic cancer - and plans to commence Phase IIa clinical trials before the end of 2005 to evaluate and safety and tolerability of the treatment. The trial will also monitor the efficacy of the treatment based on CT measurements of tumor regression as a foundation for subsequent Phase IIb dose-profiling studies.

Finally, pSivida will employ a multi-injector/implanter device that will be clinically evaluated in all subsequent trials using BrachySilTM as a means of ensuring effective distribution of the implanted dose from a single entry point. This device will, for the first time, enable physicians to treat larger tumors and could represent a significant advantage of BrachySilTM over existing brachytherapies. The Company is currently seeking development and marketing partners for BrachySilTM in the major territories.

Notes on BrachySil[™] and competitive advantages in brachytherapy

BrachySilTM (32-P-BioSiliconTM) is being manufactured to regulatory guidelines by supply chain contract partners including Atomising Systems Ltd and High Force Ltd in the UK and Auriga Medical in Germany. Importantly the manufacturing process has already been scaled up successfully to supply materials for clinical trial programmes and early product launch.

Brachytherapy treatment utilising BrachySil™ includes the following potential advantages:

- Short range 32-P isotope has a short active range resulting in controlled exposure to radioactivity and less damage to healthy tissue.
- Immobilization 32-P device is immobilized in the tumor, significantly reducing risk of leakage or systemic side effects.
- · Ease of application BrachySil™ is delivered under local anaesthetic 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 32-P half-life of 14 days allows convenient distribution to hospitals and application in the patient.
- Manufacture BioSilicon[™] is "radiation hard" allowing ease of manufacture of BrachySil[™] from phosphorus-doped silicon used in the electronics industry without the need to build costly manufacturing facilities.

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NOTES TO EDITORS:

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 BioSiliconTM. As a new and exciting biocompatible material, BioSiliconTM 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 BioSiliconTM for use in or on humans and animals. The IP portfolio consists of 26 patent families, 30 granted patents and over 80 patent applications. The core patent, which recognises BioSiliconTM 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 <u>www.qinetiq.com</u>.

For more information visit www.psivida.com

Singapore General Hospital

Singapore General Hospital (SGH) is Singapore's oldest and largest tertiary acute care hospital and national referral centre. It offers a comprehensive range of clinical specialties and support services for the South-East Asia region. Annually, 70,000 patients are admitted to the hospital and 600,000 attend its specialist outpatient clinics. SGH also recognizes research and education as essential pillars of healthcare. Drawing upon its wealth of resources (clinical expertise, modern research facilities, and patient data and specimens), the Hospital's researchers are pursuing, in an integrated and holistic manner, the full range of 'molecules-to-communities' studies. Extensive teaching and educational services are also offered.

For more information visit www.sgh.com.sg

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 BioSiliconTM 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.