## 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 March 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 o	check mark whether the	e registrant files o	r will file annual reports	s under cover Form 20-F	or Form 40-F).

Form 20-F ⊠ 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: March 11, 2005 By: /s/ Aaron Finlay

Aaron Finlay
Chief Financial Officer and Company Secretary

# **EXHIBIT INDEX**

**EXHIBIT 99.1:** Shareholder Update March 2005



# SHAREHOLDER UPDATE March 2005

Dear Shareholder,

The past six months has been a busy and exciting period for pSivida with a number of significant events occurring throughout this period.



In January your Company became truly global with pSivida listing on NASDAQ's National Market joining only eleven other Australian companies listed on one of the world's premier capital markets. With its NASDAQ listing completed your Company is actively seeking to increase its presence and capabilities in the US, the world's most important pharmaceutical and capital market. pSivida is looking to appoint a US based CEO and Business Development executive to assist with accelerating the commercialization efforts for BioSilicon<sup>TM</sup>.

The awareness of pSivida in the US has been steadily growing with increasing coverage in US-based investor newsletters and industry publications such as NanoBiotech News and the Forbes/Global Nanotech Report. pSivida has also been asked to present at upcoming investor based conferences in March and April following a successful presentation at the Brean Murray & Co Annual Institutional Investor Conference in New York in early February. Your Company is currently in the US conducting a series of investor seminars for both retail and institutional investors in an effort to increase US-based investment in your Company.

Importantly your Company also continues to make excellent progress with the development of its lead product BrachySil<sup>TM</sup>, for the treatment of inoperable primary liver cancer by effectively delivering radiation directly to the tumor. Further interim data released in February from the current Phase IIa clinical trial showed that BrachySil<sup>TM</sup> led to significant regression of tumors. The results revealed an average reduction in tumor size of 80% with some small tumors disappearing completely. These results are particularly pleasing given the significant level of tumor regression

achieved despite the low dose being administered in the trial. As one of the few available technologies that deliver a radioisotope directly to tumours, BrachySil<sup>TM</sup> has also shown to be safe, a problem associated with some other tumour-targeted treatments. Importantly no treatment related adverse events were reported in these patients.

These studies represent a critical milestone in pSivida's product development plans and lay the foundations for the process leading to registration of BrachySil<sup>TM</sup>, our lead product. Following the completion of the Phase IIa trial your Company expects to commence a dose profiling study and pivotal registration trials for the product during 2005. BrachySil<sup>TM</sup> is expected to be registered as an approved treatment for liver cancer potentially as early as 2007.

In line with the broader strategy for the development of BrachySil<sup>TM</sup> your Company is looking to significantly expand the use of BrachySil<sup>TM</sup> for other solid tumour cancers, ultimately producing a pipeline of BioSilicon<sup>TM</sup> based oncology products. This strategy will substantially broaden the market potential of the product well beyond the possibilities for current brachytherapy and embolisation approaches. The selection of these indications has resulted from considerable consultation with the Company's Oncology Advisory Panel and significant research into the potential market size and competitive landscapes that exist for cancer treatment in these areas.

As a first step in this process and in parallel to the development of BrachySil<sup>TM</sup> for primary liver cancer, your Company aims to commence a human clinical trial for a second cancer indication such as pancreatic cancer, within the next year. Importantly a manufacturing and supply chain compliant to worldwide regulatory guidelines has already been established for BrachySil<sup>TM</sup>, eliminating a costly and time-consuming component in the development of future BrachySil<sup>TM</sup> products.

Your Company is currently seeking and is in discussions with development and marketing partners in an effort to maximise the future return to shareholders for BrachySil<sup>TM</sup>. Your Company is seeking to share some of the risks and costs associated with taking this product through to registration and ultimately to market, although we have the expertise and financial capacity to take BrachySil<sup>TM</sup> to product registration alone should we choose to do so.

Other recent milestones for pSivida include:

- The signing of a deal with a top five global pharmaceutical company to evaluate pSivida's BioSilicon<sup>TM</sup> technology for drug delivery. The undisclosed pharmaceutical company will fund the evaluation of BioSilicon<sup>TM</sup> in the controlled release of a number of compounds. It is expected that this deal is the first of a number of potential similar deals to be signed with other pharmaceutical companies during the year.
- The signing of an agreement with ITOCHU Corporation of Japan, to develop and commercialise BioSilicon<sup>TM</sup> products in Japan and Asia. The Agreement is an important one as ITOCHU is one of Japan's largest companies and the deal covers opportunities for production, distribution, direct investment, licensing and co-operative development programmes as well as the development of entirely new applications for BioSilicon<sup>TM</sup>.
- · The creation of Australian based subsidiary AION Diagnostics Limited for a planned future spin off, which will develop diagnostic applications for BioSilicon<sup>TM</sup>. Your Company appointed Dr Anna Kluczewska as MD of AION.

In other news, pSivida appointed a new R&D Director. Dr Mark Parry-Billings is a former Director of R&D at Innovata Biomed and has held senior roles at Schering Healthcare (UK). The appointment allows Chief Scientific Officer, Dr Leigh Canham to concentrate on strategic developments associated with BioSilicon<sup>TM</sup> including new manufacturing methods, 'smart devices' and general technical support for your Company's drug delivery program.

Your Company's UK based operations have grown substantially over the last 12 months with a current staff of 22 including some 15 PhDs. This has been necessary to meet the increasing commitments involving the later stage development projects we are currently working on, to expand our BioSilicon<sup>TM</sup> technology platform especially in drug delivery, including the work for the undisclosed top five global pharmaceutical company and also to support some of our other collaborative programmes.

pSivida has also strengthened its patent positions with a new European patent granted for 'Biomirrors', a novel form of BioSilicon<sup>TM</sup> that can be used in the blocking of light as a means to protect the skin from harmful UV rays. In addition a European patent was granted for the oral delivery of BioSilicon<sup>TM</sup> and, in the US, a patent was granted for silicon fabricated products which overcomes the problems normally associated with the damage to circuits caused by high temperature welding.

Importantly your Company's focus remains the application of BioSilicon<sup>TM</sup> in controlled release in drug delivery, exploiting this truly unique biomaterial's many wonderful and exciting properties. We have been using a similar consultative process to that which we employed with BrachySil<sup>TM</sup>, consulting clinicians and market researchers to explore other potential drug delivery applications for our technology. We are planning and progressing the necessary preclinical studies which will enable us to embark on these with a minimum of delay.

Updates on the progress of the top five global pharmaceutical company's evaluation of BioSilicon<sup>TM</sup> for drug delivery are expected throughout the year. It remains the Company's expectation that on the basis of successful outcomes from this, and other similar evaluations that we expect to be carrying out, it will be in a position to secure licensing agreements for the use of BioSilicon<sup>TM</sup> in delivering drugs for partner companies in the pharmaceutical and biotechnology sectors.

pSivida has had an excellent start to 2005. We at pSivida thank you for your continued support and look forward to achieving milestones such as the completion of the Phase IIa trial and the commencement of pivotal registration trials for BrachySil<sup>TM</sup> as well as further strengthening of the Company's patent position, a growing international profile and the maturation of your Company's planned spin out, the newly created AION Diagnostics.

Yours Sincerely.

Gavin Rezos, Managing Director

pSivida Limited

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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<sup>TM</sup> 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<sup>TM</sup> 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  $BioSilicon^{TM}$ . 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.

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<sup>TM</sup>.
- · Dr Anna Kluczewska, 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

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: the inability to attract the required staff in the US; the inability to reach agreement with prospective development and marketing partners; and 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.