

# 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 January 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: January 31, 2005

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

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**EXHIBIT INDEX**

<b>EXHIBIT</b>	pSivida Quarterly Cashflow - December 2004; Commentary and Highlights
<b>99.1:</b>	
<b>EXHIBIT</b>	Appendix 4C - Quarterly report for entities admitted on the basis of commitments
<b>99.2:</b>	

## pSivida Quarterly Cashflow – December 2004 Commentary and Highlights

Global nanotechnology company pSivida Limited, is pleased to release its quarterly cashflow statement for the quarter ending 31 December 2004.

### Highlights and Announcements for the Quarter

#### Top 5 Global Pharmaceutical Company to Evaluate BioSilicon™ for Drug Delivery

In December pSivida signed an agreement with an undisclosed top 5 global pharmaceutical company for the staged evaluation of BioSilicon in drug delivery. The agreement covers the evaluation of BioSilicon for the controlled release of a number of selected compounds. The pharmaceutical company will fund the direct costs of the programme. The company expects to announce similar agreements with other pharmaceutical companies during 2005.

#### ITOCHU –Development and Commercialization of Products in Japan & Asia

An agreement was signed with one of the world's largest companies, ITOCHU Corporation of Japan, to develop and commercialize BioSilicon in Japan & Asia. The agreement covers opportunities for production distribution, direct investment, licensing and co-operative development programmes. While the agreement will initially focus on pSivida's existing potential applications including BrachySil™, the agreement also provides for the development of new ingestible BioSilicon products in the rapidly growing area of food technology, where ITOCHU has considerable experience.

#### Positive Interim Clinical Trial Results for BrachySil

During October pSivida announced interim data analysis from its Phase IIa trial for BrachySil being conducted at Singapore General Hospital. The interim results confirmed expectations that BrachySil is safe and effective at tumor regression. The first 4 patients, all with inoperable liver cancer, showed no product related side effects and up to 60% regression of tumors.

The trial results to date have established 4 key findings:

- **SAFETY – No product related adverse events**  
BrachySil is administered directly into the tumor restricting radioactivity to the tumor itself.
- **EFFICACY – Treated tumors demonstrate significant tumor regression**  
The primary objective of the trial is to determine the safety profile of BrachySil, although efficacy was also demonstrated with CT scans of tumors at the time of treatment and 3 months later indicating significant tumor regression in all targeted lesions with a maximum regression of 60% from the dose used in the trial.
- **SPECIFICITY – Retention of radioactivity**  
A key outcome from the interim trial results was that the BrachySil nanostructured micro particles remained in the tumor with no or insignificant leakage.
- **EASE OF APPLICATION – Practical and rapid treatment of tumors with ultrasound and CT guidance**  
Simple and accurate procedure for the treatment of solid tumors. A multi injector is in the design phase to treat larger tumors with multiple implantations from a single entry point.

Further interim results from the current Phase IIa clinical trial are expected to be announced in February 2005.

#### Appointment of New Research & Development Director

In November pSivida appointed Dr Mark Parry-Billings as Research & Development Director of its UK based operating subsidiary. Dr Parry-Billings is a former Director of R&D at Innovata Biomed and has also held senior roles at Schering Healthcare in the UK. The appointment of Dr Parry Billings will allow pSivida's Chief Scientific Officer, Prof. Leigh Canham to concentrate on the strategic development aspects of the BioSilicon platform including new manufacturing methods, 'smart devices' and general technical support to our activities in drug delivery. pSivida's R&D capabilities were further strengthened during the quarter with the appointment of an additional five PhD scientists.

#### New European Patent Granted – Dermatological Applications for BioSilicon

European Patent Number 1309309 relates to the invention of formulations that contain microscopic (micron sized) silicon particles known as 'Bio-mirrors', a novel form of BioSilicon that can reflect or block light at predetermined selective wavelengths. This patent specifically relates to the topical use of such Bio-mirrors as a means of protecting the skin from the detrimental effects of certain wavelengths of light where effective sunscreens are a vital component of daily protection against skin cancer and premature aging. An additional advantage of such Bio-mirrors is the potential ability to load the BioSilicon particles with suitable dermatological agents and for the particles to be safely absorbed by the skin, dissolving into silicic acid which is commonly found in everyday foods.

### Post Quarter Highlights and Announcements

**pSivida Lists on NASDAQ's National Market** pSivida is now listed and has commenced trading in the US on NASDAQ's National Market via a Level II American Depositary Receipts (ADR) programme. Trading commenced in pSivida's American Depositary Shares (ADS) on Thursday 27<sup>th</sup> January 2005 under the ticker symbol PSDV. The ADSs trade on a ratio of 10:1, that is one ADR represents 10 ordinary pSivida shares. pSivida continues to trade on the Australian and Frankfurt stock exchanges. A series of informational meetings in the US are being scheduled during February and March for investors and potential investors.

## 4<sup>th</sup> US Patent Granted

US Patent Number 6,832,716 provides protection for silicon fabricated products composed of bonded BioSilicon wafers and related devices. One of the key problems in constructing hermetically sealed devices is that welding of silicon-based components containing integrated circuits can often result in damage to the circuit. This new patent grant addresses the novel concept of low temperature welding associated with nanostructured silicon. This important technology provides for a method of producing sealed circuitry in association with BioSilicon, thus enabling the production of 'smart', processor-based devices. More specifically, this technology enables the potential production of tablets or implants that contain a processor capable of regulating a wide variety of required drug delivery characteristics.

-ENDS-

### Released by:

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Investor Relations  
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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 BioSilicon™. As a new and exciting biocompatible and biodegradable 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, royalty free 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: regulatory issues involving the SEC and/or the NASDAQ Stock Market. 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.

**Appendix 4C**  
**Quarterly report**  
**for entities admitted**  
**on the basis of commitments**

Introduced 31/3/2000. Amended 30/9/2001

Name of entity  
PSIVIDA LIMITED

ABN  
009 232 026

Quarter ended ("current quarter")  
31 DECEMBER 2004

**Consolidated statement of cash flows**

<b>Cash flows related to operating activities</b>	Current quarter \$A	Year to date (6 months) \$A
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) staff costs	(417,389)	(662,160)
(b) advertising and marketing	-	-
(c) research and development	(1,455,140)	(3,443,948)
(d) leased assets	-	-
(e) other working capital	(824,772)	(1,310,823)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	173,632	381,999
1.5 Interest and other costs of finance paid	(1,110)	(2,886)
1.6 Income taxes paid	-	-
1.7 Other	(32,490)	(23,413)
- GST (paid)/received	233	13,880
- Other Income	-	-
<b>Net operating cash flows</b>	<b>(2,557,036)</b>	<b>(5,047,351)</b>

+ See chapter 19 for defined terms.  
30/9/2001

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**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter \$A	Year to date (6 months) \$A

1.8	Net operating cash flows (carried forward)	(2,557,036)	(5,047,351)
	<b>Cash flows related to investing activities</b>		
1.9	Payment for acquisition of:		
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	(825,912)	(1,459,773)
	(e) other non-current assets	-	-
1.10	Proceeds from disposal of:		
	(a) businesses (item 5)	-	-
	(b) equity investments	-	-
	(c) intellectual property	-	-
	(d) physical non-current assets	-	-
	(e) other non-current assets	-	-
1.11	Loans from/(to) other entities	-	-
1.12	Loans repaid by other entities	-	-
1.13	Other (provide details if material)		
	- Cash paid for equity increase in controlled entity	(4,291,377)	(11,689,402)
	- Net cash held by subsidiary on acquisition	4,291,377	7,044,436
	<b>Net investing cash flows</b>	<u>(825,912)</u>	<u>(6,104,739)</u>
<b>1.14</b>	<b>Total operating and investing cash flows</b>	<u>(3,382,948)</u>	<u>(11,152,090)</u>
	<b>Cash flows related to financing activities</b>		
1.15	Proceeds from issues of shares, options, etc.	3,366,500	3,666,500
1.16	Proceeds from sale of forfeited shares	-	-
1.17	Proceeds from borrowings	-	-
1.18	Repayment of borrowings	-	-
1.19	Dividends paid	-	-
1.20	Other - Share issue costs	-	(27,422)
	<b>Net financing cash flows</b>	<u>3,366,500</u>	<u>3,639,078</u>
	<b>Net increase (decrease) in cash held</b>	(16,448)	(7,513,012)
1.21	Cash at beginning of quarter/year to date	23,023,627	31,350,656
1.22	Exchange rate adjustments	(727,024)	(1,557,489)
1.23	<b>Cash at end of quarter</b>	<u>22,280,155</u>	<u>22,280,155</u>

+ See chapter 19 for defined terms.

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**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

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**Payments to directors of the entity and associates of the directors**

**Payments to related entities of the entity and associates of the related entities**

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Current quarter  
\$A

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1.24 Aggregate amount of payments to the parties included in item 1.2

181,621

1.25 Aggregate amount of loans to the parties included in item 1.11

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1.26 Explanation necessary for an understanding of the transactions

1.2(a)	Staff costs include consultants and directors fees paid by pSivida.
1.2(c)	Research and development costs include all expenditure incurred by pSiMedica and pSiOncology.
1.13	Includes amounts transferred for the purposes of funding the research and development activities of pSiMedica.
1.15	\$3,366,500 received on the exercise of options with an expiry date of 31 December 2004.

**Non-cash financing and investing activities**

2.1	Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows
	N/A
2.2	Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest
	N/A

**Financing facilities available**

Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).

	Amount available \$A	Amount used \$A
3.1 Loan facilities	-	-
3.2 Credit standby arrangements		
- Equity Line of Credit Facility	7,500,000	-

+ See chapter 19 for defined terms.  
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**Appendix 4C**

**Quarterly report for entities  
admitted on the basis of commitments**

**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.

	Current quarter \$A	Previous quarter \$A
4.1 Cash on hand and at bank	927,580	401,825
4.2 Deposits at call	21,352,575	22,621,802
4.3 Bank overdraft	-	-
4.4 Other (provide details)	-	-
<b>Total: cash at end of quarter (item 1.23)</b>	<b>22,280,155</b>	<b>23,023,627</b>

**Acquisitions and disposals of business entities**

	Acquisitions <i>(Item 1.9(a))</i>	Disposals <i>(Item 1.10(a))</i>
5.1 Name of entity		
5.2 Place of incorporation or registration		
5.3 Consideration for acquisition or disposal		
5.4 Total net assets		
5.5 Nature of business		



**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does ~~does not~~\* (*delete one*) give a true and fair view of the matters disclosed.

31 January 2005

Sign here: \_\_\_\_\_ Date: \_\_\_\_\_  
(Director/Company secretary)

Aaron Finlay

Print name: \_\_\_\_\_

+ See chapter 19 for defined terms.  
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**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

**Notes**

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

+ See chapter 19 for defined terms.  
30/9/2001

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