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 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.

Date: February 17, 2005

pSivida Limited

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

EXHIBIT INDEX

EXHIBIT 99.1: Open Briefing. pSivida. Strategy Director on Phase IIa Interim Trial Data

Attention ASX Company Announcements Platform
Lodgement of Open Briefing

pSivida Limited
Level 12, BGC Building
28 The Esplanade
Perth, Western Australia 6000

Date of lodgement: 17-Feb-2005

Title: Open Briefing. pSivida. Strategy Director on Phase IIa Interim Trial Data

Record of interview:

corporatefile.com.au
pSivida Limited announced on 15 February 2005 further interim data from the Phase IIa clinical trial of its lead product BrachySil™. The results have further demonstrated safety and tumor regression in inoperable primary liver cancer patients. Could you explain the significance of this data?

Director for Strategy, Dr Roger Aston
This data demonstrates that the product we've created using a radioisotope can be administered safely and accurately into tumors, producing significant tumor regression. The average regression in this second patient group was 80 percent, with 100 percent regression observed in some smaller tumors. This is something I believe we've not seen with other intra-tumoral approaches.

Intra-tumoral therapy is still not common. With the exception of prostate brachytherapy, there are no products currently available which can tackle tumors through the direct delivery of the product into the tumor. In fact, many of the other products available which have been used to undertake intra-tumoral therapy are associated with safety issues.

corporatefile.com.au
What's the objective of this Phase IIa trial and how has it been funded?

Director for Strategy, Dr Roger Aston
The objective of our Phase IIa trial in cancer patients was to show that our product BrachySil™ is safe. We have to show that it doesn't cause unacceptable side effects. As most people are aware, side effects are commonly suffered by cancer patients as a result of chemotherapy and radiotherapy.

More specifically, we undertook this trial to show that, firstly, we could place BioSilicon™ particles into the tumor, and secondly, that these particles are retained within the tumor without any leakage of radioactivity into the healthy tissue surrounding the tumor and into the blood circulation of the patient. And in so doing, we believed that the implanted material would be effective in causing tumor regression. These Phase IIa interim trial results have clearly shown that we've managed to achieve this.

This trial was completely funded by pSivida. We have great expectations for BrachySil™ and we believe it's important for us to retain as much ownership of this product as possible. We can take BrachySil™ through to product registration which could potentially occur as early as 2007. Given our core focus is drug delivery and BrachySil™ is a lead product only, we could consider commercialization partners at an earlier stage. With a current cash balance of $20 million, we have sufficient cash reserves to fund these registration trials.

corporatefile.com.au
Where has the trial been conducted and by whom?

Director for Strategy, Dr Roger Aston
The trial is being performed at the Singapore General Hospital, a collaborative partner, which offers the technical capability, the latest technology in terms of tumor imaging equipment and CT scanning, and the ability to recruit the right patients for this trial relatively quickly. It's one of the top medical establishments in Singapore, housing a highly capable team of experts dedicated to treating liver cancer patients through a variety of methods.

Associated with the incidence of hepatitis, liver cancer is very common in Asia; in some Asian countries hepatitis is endemic with incidence as high as 10 percent. That's why patients could be recruited fairly quickly for this particular trial.

corporatefile.com.au
How many patients were recruited?

Director for Strategy, Dr Roger Aston
This was a small trial, designed to satisfy regulators on safety issues for an intra-tumoral product in late stage cancer and involved a total of eight patients.

This kind of trial can be done in a small number of patients because it is intra-tumoral, unlike a trial relating to a new chemotherapy drug which would involve a larger number of patients, whereby the drug is administered to the whole body and thus would require the monitoring of side effects in a larger group.

corporatefile.com.au
How have you monitored the performance of BrachySil™ during the trial? What's the expected duration of this trial and when do you expect to provide the final report?

Director for Strategy, Dr Roger Aston
The specific design of this trial enabled us to actually look at and measure the size of individual tumors, allowing us to assess very clearly the performance of our product on a tumor-by-tumor basis. This means we could involve just a small number of patients and get a fairly hard clinical end point.

From start to finish, the trial was designed to cover a period of six months, meaning we have to monitor each of the eight patients for six months after their treatment.

The key data we provided to the market this time showed the first three-month post-treatment observations for the second group of four patients; we already did this in relation to the first four patients last October.

We aim to provide a final report of the Phase IIa trial results to the market in three months' time, after completing the second three-month post-treatment observation period, thus completing the formal six-month reporting period of this trial.

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Could you summarise for us how BrachySil™ actually works?

Director for Strategy, Dr Roger Aston
The products in the market at the moment in brachytherapy are for prostate cancer. Our product is initially for liver cancer but we are studying additional markets for solid tumor cancers, with the aim of commencing a human clinical trial for a second indication for BrachySil™ within the next year..

Unlike seeds for prostate cancer, BrachySil™ is a micron-sized BioSilicon™ particle in which the isotope 32 phosphorus (32-P) is immobilised. What this means in simple terms is that our product is basically a silicon particle that contains an isotope. It's based on our BioSilicon™ technology which is nano-structured - one nanometer is one billionth of a meter.

The 32-P isotope we're using is an extremely powerful beta-emitter with a kill range of about a 2 to 3 cm in diameter in water or tissue. We place particles as specific point sources into the middle of a tumor, which then results in the destruction of everything within a range of between 2 to 3 cm in diameter through radiation as beta particles are emitted.

In the case of small tumors, we aim to regress them completely. In the case of larger tumors, we would need to use point sources in a number of places in the tumor to ensure that our product destroys the whole tumor.

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In summary, what do you regard as the key advantages of BrachySil™?

Director for Strategy, Dr Roger Aston
We've identified seven main competitive advantages.

First of all, our product has a short kill range which makes it versatile and results in less damage to healthy tissue.

Secondly, our product significantly reduces the risk of radiation leakage or systemic side effects because of the fact that 32-P is immoblised within BrachySil™ in the tumor. It's worth noting that alternative biomaterials such as polymers and metals cannot carry 32-P using our manufacturing process. Moreover, polymers are seriously damaged by radiation and aren't suited to isotope-based products. In contrast, BrachySil™ is manufactured in a reactor while being exposed to neutron radiation. Our material BioSilicon™ is radiation hard, meaning it, as the carrier, isn't affected by the radiation in the manufacturing process to convert phosphorus into P-32. Silicon is one of the few elements which is radiation hard.

Thirdly, it's easily administered, requiring only local anesthetic, thus allowing patients to be released from hospital the next day, in contrast to some of the other more traumatising brachytherapy procedures involving the administration of seeds. The procedure using BrachySil™ can take between 25 minutes and 45 minutes, after which the patient is retained for a 24-hour observation period before being discharged.

Fourthly, BrachySil™ is designed exclusively for intra-tumoral delivery, meaning a direct delivery to the tumor without affecting surrounding healthy tissue. This is achieved through a fine bore needle which minimises haemorrhaging and tissue trauma.

Fifthly, it allows the potential targeting of a wide variety of cancer tumors, unlike current brachytherapy products that are essentially for prostate cancer only.

Sixthly, the 32-P radioisotope has an active half-life of 14 days allowing a relatively convenient timeframe for distribution logistics and supply to hospitals, in stark contrast to other isotopes used in brachytherapy which have a half-life of 64 hours and are consequently more difficult to handle in terms of logistics or time. Thus, BrachySil™ offers a slow progressive tumor kill which we believe is preferable to other approaches.

Lastly, neutron transmutation allows the easy manufacture of BrachySil™ from phosphorus-doped silicon, which is actually used in the electronics industry as a semi-conductor.

Silicon has been used in the electronics industry for over 40 years in the manufacture of silicon chips and it is an abundant material comprising a third of our planet's crust in the form of silicon oxide. We can therefore procure silicon for the manufacture of BioSilicon™ and BrachySil™ very cheaply. By comparison, brachytherapy seeds cost about US$50 each, with a patient requiring around 50-150 seeds during a prostate cancer treatment.

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In pSivida's Open Briefing on 22 December 2004, MD Gavin Rezos mentioned that you're planning for BrachySil™ to enter a Phase IIb trial targeting either pancreatic, ovarian or bladder cancer. Is that still your plan?

Director for Strategy, Dr Roger Aston
Yes, we are of course interested in using our product in a variety of cancers. This would make sense if you have a product such as ours which can be administered intra-tumorally and result in the regression of tumors that are not surgically removable.

The difficulty with chemotherapy is that sooner or later patients become resistant to the therapeutic benefits, and in such instances there are few alternatives available to them. In the case of pancreatic cancer for example, most patients who are admitted to hospital have reached a stage of cancer progression where the tumor is inoperable. In the case of brain cancer, for example, it's often extremely difficult to treat the tumor because of its location.

A key advantage of BrachySil™ is a very defined kill range, enabling a very accurate determination of the extent of the damage being inflicted on any surrounding tissue in the treatment process. We regard this advantage as an important safety factor for the potential use of our product, particularly in cancer where surrounding tissue damage is critical to the outcome.

We're interested in taking BrachySil™ to the market for an important oncology indication, liver cancer, but we do expect that once it's registered for this specific indication, there could be a number of other applications which physicians and radiologists could consider when assessing our product in their arsenal against cancer.

We expect to commence Phase IIa trials on another solid tumor cancer, such as pancreatic cancer, within the next year. Pancreatic cancer has a very low survival rate and there is an enormous demand for products in this area.

Other cancers we'd target are some of the more specialised cancers such as brain cancers, where we believe our product offers unique advantages over external beam radiation and chemotherapy. But there's no reason why we shouldn't also target some of the more common cancers, such as breast cancer, in due course.

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Your announcement indicates you expect to begin dose profiling studies and pivotal registration trials for BrachySil™ in 2005 following the completion of the Phase IIa trial. Why do you believe a much shorter development and registration timeframe is feasible?

Director for Strategy, Dr Roger Aston
We've had verbal confirmation from a major regulatory authority that BrachySil™ is expected to be categorised as a "device" instead of a "drug". Because the registration process is typically shorter than the regulatory process involving a pharmaceutical drug, we believe a shorter timeframe is feasible.
We'll be required to submit a "CE mark application" which is essentially a device-based application for registration as opposed to an application relating to a drug and we will target a global registration strategy, covering the US, Europe, Asia and Australia.

corporatefile.com.au
What will trigger the start of your planned registration trials in Asia, Europe and the US in 2005? How long will this trial last?

Director for Strategy, Dr Roger Aston
The completion of the dose profiling study will trigger the start of registration trials.

The dose profiling study is specifically geared to identifying the optimum dose but many factors, such as the actual procedures for administration and the syringe assemblies, are going to be much the same in the dosing study as in the registration trial. In addition, many of the activities for the registration trial can start fairly early, such as preparing protocols or planning how to run the trial. Therefore, a lot of parallel processing can and will take place.

Parallel processing should enable us to start the registration trial in the latter part of 2005, immediately after we complete and receive the data for the dosing study. Key data from the registration trial will be derived from 6-month post treatment scans. The registration process is expected to be completed for a filing with the regulatory authorities by early 2007.

corporatefile.com.au
What regulatory hurdles do you anticipate before commercialization?

Director for Strategy, Dr Roger Aston
Regulatory authorities will want to see clear deliverable value in this product. The Phase IIa clinical trial data we have to date has given us a lot of confidence in our product. We've shown a very high degree of safety, with no radioactive leakage. We've also shown significant tumor regression.

Going forward, we'll have to demonstrate that the degrees of tumor regression we're achieving are clinically beneficial to the patient, and this is where trial design will be critical.

Demonstrating regression is going to be a key objective and we take comfort from the fact that in this current trial we've shown 100 percent regression in certain tumors; in other words, tumors appear to have been eliminated completely after only three months.

corporatefile.com.au
When do you expect to take BrachySil™ to market? What commercialization strategy will you be likely to pursue?

Director for Strategy, Dr Roger Aston
We're interested in filing and registering this product ourselves, so we'll conduct and fund the US, European and Asian trials ourselves.

Once we've demonstrated the value of this product and have obtained its registration, we'll have two options: we'll either set up a marketing organization or get a marketing partner who has a well-established global distribution and logistics system for radio-pharmaceuticals.

We plan to take our product to market in 2007. Timelines for these clinical and regulatory processes are fairly well established. However, as I said earlier, we are a drug delivery company and BrachySil™ is a lead product only. Consequently, we would consider earlier stage partnering opportunities.

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pSivida commenced trading on the NASDAQ through its Level II ADR programme on 27 January 2005. Why did you list on NASDAQ?

Director for Strategy, Dr Roger Aston
We felt very strongly that we needed to be a player in the US market, particularly as we move towards the later clinical trials for our product.

If you look at the valuations of US companies and corresponding European, Japanese or Australian companies, there's much better recognition of value as you succeed through Phase II with your product in the US. We want to deliver maximum value to our shareholders and we see listing on the NASDAQ as a key part of that strategy with liquidity now starting to build.

Apart from the ASX and NASDAQ, we're also listed on the Frankfurt Stock Exchange through the XETRA system and the OFEX International Market Service (IMS) in the UK.

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Are you seeking fresh capital?

Director for Strategy, Dr Roger Aston
We are in a strong cash position with around $20 million in the bank which will more than adequately cover our immediate clinical trial needs for BrachySil™ and our other areas of BioSilicon™.

Because of the diverse applications of BioSilicon™, we're expecting some revenues in the near future from partnering and licensing activities.

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What's your cash burn? What's your R&D-to-expense ratio?

Director for Strategy, Dr Roger Aston
Our consolidated operating cash burn is about $0.7 million per month. Our R&D-to-expense ratio is a very credible 77 percent.

For more information about pSivida Limited, view www. psivida.com or call Joshua Mann on +(61-8) 9226 5099.

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