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# Diagnostics Business Strategy Aligned for Development of Leading Diagnostic Products

Global nanotechnology company pSivida Limited **(ASX:PSD)** is pleased to announce the Company's development and commercialisation strategy for the newly acquired Diagnostics Business.

Following intensive market sector evaluation and product positioning, pSivida has chosen cancer testing as its first core diagnostic indication area, utilising the basic principles of immunodiagnostics transferred to an in-vivo point of care device.

Key highlights of the commercialisation strategy include:

- Strong positioning in large diagnostic market sectors with significant advantages over current diagnostic products
- Alignment of core diagnostic focus with current therapeutic product development
- Strong foundation and expertise on GMP manufacture of BioSilicon™ structures, toxicology, in-vivo biodegradation and safety from current brachytherapy business
- Development of core therapeutic focus area will provide solid foundation for rapid penetration into other disease areas by internal development, collaborations and/or out-licensing
- Leading European science and engineering research institution support

pSivida has acquired from pSiMedica a global exclusive license to use BioSilicon™ for "in the body" diagnostics and a first right of refusal over "on the body" diagnostics structured on BioSilicon™. pSivida has also recently signed a Licensing Agreement with Forschungszentrum for the use of its porous silicon optical mirror technology. Combining these technologies pSivida intends to commercialise BioSilicon™ optical mirrors as an in-vivo diagnostic device, with the ability to provide early diagnosis and continual monitoring with an initial focus on cancer testing.

**Market evaluation**

The total diagnostic market was valued at US$22.8 billion in 2002 with pSivida's potential addressable market standing at US$13.1 billion or 58%. Key market sectors applicable to the BioSilicon™ technology include home/self testing valued at US$5 billion (22% of total market), immunodiagnostics at US$6 billion (largest market sector at 25 % of total market), point-of-care testing totaling US$1.1 billion (6% of total) and cancer testing which brought in a total of US$1 billion and accounted for 5% of the total market. BioSilicon™ diagnostic technology offers significant competitive advantages across all selected market sectors.

Opportunities for improvement and research focus in diagnostics have been directed toward personalised medicine enabling earlier diagnosis, quicker feedback, ease-of-use and continual monitoring for the onset and management of disease states.

**BioSilicon™ Diagnostics - Strong Competitive Advantages**

BioSilicon™ technology has significant advantages offering a cheap, safe and biodegradable device implanted under the skin, able to provide early and immediate feedback through a simple hand-held detector.

Many cancers are detectable through chemical markers released into the bloodstream usually detected by diagnostic tests in pathology laboratories. By placing porous silicon mirror particles, smaller than a pin-head, containing quantities of targeted antibody, the antibody capture mechanism would generate a change in reflectivity as the relevant marker accumulates on the BioSilicon™ surface. This change would be externally detected by the patient. The accumulation mechanism could potentially provide greater sensitivity than ex-vivo diagnostics with earlier detection of cancer.

pSivida Manager for Diagnostics Business Development, Dr. Anna Kluczewska said, "We are extremely pleased to be embarking on a development program where the product has strong differentiation and significant patient advantages over existing as well as developing products."

The controlled biodegradable nature of the material would allow further administrations at different sites.

**Commercialisation strategy**

pSivida Director Research and Commercialisation, Dr. Roger Aston said, "We will initially focus on proof-of-concept studies for the cancer testing sector using in-vivo immunodiagnostic principles. Concurrently, pSivida will be exploring opportunities to co-develop and/or out-license the technology into other therapeutic areas thereby leveraging the BioSilicon™ diagnostic technology for multiple therapeutic markets."

The long-term strategy includes development of a portfolio of BioSilicon™ diagnostic products offering early diagnosis and therefore improved disease prognosis, continual monitoring of chronic and acute conditions available as cheap and easy-to-use point of care devices.

pSivida's technology is protected by various granted patents and patent applications that provide protection for the scope of the work to be undertaken.

**-ENDS-**

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**NOTES TO EDITORS:**

**pSivida Limited**

pSivida is an Australian-based biotechnology company committed to the biomedical applications of nano-technology and which has as its core focus the development and commercialisation of nano-structured porous silicon (BioSilicon™) in biocompatible and biodegradable forms for use in human and animal healthcare through its UK subsidiary pSiMedica Limited, and in conjunction with UK Government owned QinetiQ plc. As a true 'platform technology', BioSilicon™ has multiple potential applications across the high growth healthcare sector, including controlled drug delivery, brachytherapy, tissue engineering and orthopaedics.

pSivida is listed on the Australian Stock Exchange (**ASX Code: PSD**). www.pSivida.com.au

**pSiMedica Limited (UK)**

pSiMedica has identified a biocompatible and biodegradable form of silicon (BioSilicon™). The technology is based on applying a modified form of the silicon chip (porosified or nano structured silicon) in a variety of healthcare applications, ranging from controlled drug delivery, brachytherapy, tissue engineering and orthopaedics to biofiltration and clinical diagnostics.

pSiMedica's market strength lies in its international management and science team, including former Chairman of SmithKline & French Research, Dr Roger Brimblecombe, former PepTech CEO Dr Roger Aston, and, the world eminent scientist and the inventor of BioSilicon™, Professor Leigh Canham. The Company has access to cutting edge research and development facilities through the UK Government's Agency QinetiQ (formerly DERA), the largest research and development institution in Europe.

pSiMedica owns the worldwide intellectual property rights to nanostructured porous silicon, known as BioSilicon™, for use in or on humans and animals and is dedicated to realising the potential of porous silicon products in areas such as controlled drug delivery, diagnostics and orthopaedics.

**QinetiQ (formerly Defence Evaluation Research Agency [DERA])**

With an annual budget of more than £800 million sterling, and the largest single research and development organisations in Europe, QinetiQ is a powerful ally for pSiMedica (UK) and pSivida. QinetiQ employs many leading scientists in its pioneering research and development which, in its heritage this century, include the invention of liquid crystal displays (LCDs), carbon fibre, the technology for flat panel speakers, infra-red sensors, night vision and microwave radar.

**Forschungszentrum Jülich GmbH**

Forschungszentrum is one of the biggest science and engineering research institutions in Europe and funded jointly by the Federal Republic of Germany and the State of Nordrhein Westfalen. Its research and development program is embedded in the superordinate program structure of the Hermann von Helmholtz Association of National Research Centers and concentrates on the five research areas of Structure of Matter, Information Technologies, Environment, Energy and Life Sciences.

Forschungszentrum has invented a porous silicon optical mirror by building up a series of layers of alternating high and low porosity silicon. This gives the alternate layers different refractive indices, so that a beam of light hitting the mirror will be reflected at the interfaces between the neighbouring layers.

For more information visit www.fz-juelich.de