

Medical Devices Fund

2014







OFFICE FOR HEALTH AND MEDICAL RESEARCH 73 Miller Street NORTH SYDNEY NSW 2060 Phone: (02) 9391 9228 Email: ohmr@doh.health.nsw.gov.au Website: www.health.nsw.gov.au

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A Message from the Minister

October 2014

The NSW Government is committed to building world class health and medical research capability in NSW. Already more than half of Australia's medical devices industry in based in NSW. Our Medical Devices Fund and commercialisation training initiatives are building on the sector to encourage and enable the translation of innovations to the benefit of patients.

The Government understands that quality medical research leads to much greater knowledge and understanding of specific diseases, new treatments and medicines, new skills, better practices and, above all, better outcomes.

The NSW Government committed \$5 million annually for the Medical Devices Fund (MDF) to support researchers and encourage further investment in new medical devices that can contribute to the discovery and application of new treatments and diagnostic techniques to improve patient outcomes. This year the NSW Government made \$7.7 million available.

To further enhance patient outcomes, this round of MDF encouraged potential applicants to engage with clinicians early in the proof of concept phase of development. Early partnerships between clinicians and researchers are important to identifying needs and maximising opportunities for translating research from bench to bedside.

As Minister for Health and Minister for Medical Research, I am passionate about medical research and ensuring that it is translated into better health outcomes for the people of this state. Once again, I am impressed by the high quality research and innovative solutions being developed within our universities and publicly funded organisations.

Our initiatives are designed to complement existing efforts to create pathways for NSW clinicians, scientists and engineers to practice and advance technologies in NSW. This year, I announced the Medical Devices Commercialisation Training Program. Another resource to help build our capability in translating medical technology in NSW.

Rapidly developing technologies are providing new ways of seeing problems and sharpening our focus on possible solutions. NSW is investing in both the equipment and skills needed to capitalise on technological advancements so that our patients and the community can benefit.

The recipients of the Medical Devices Fund will be instrumental in the application of new treatments, diagnostic techniques and devices that will be major contributors to health improvements into the future.

I offer most sincere thanks to Professor Mary O'Kane, NSW Chief Scientist and Engineer, the members of the Assessment Panel and the support staff in the Office for Health and Medical Research who provided outstanding leadership throughout the evaluation process for the NSW Medical Devices Fund 2014. To the many individuals and organisations who submitted applications this year as well as the grant recipients from last year, I thank you for your innovative ideas and persistence. Your efforts provide hope for future medical breakthroughs in NSW.

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Hon Jillian Skinner MP Minister for Health Minister for Medical Research





A Message from the Chair

October 2014

The Medical Devices Fund, established by the Minister for Health and Minister for Medical Research, is now in its second year and proving to be a very worthwhile program. The program indeed highlights a good strong industry that is innovating as fast as it is growing.

Again the Panel was delighted by the number and quality of applications received this year which were particularly strong in the areas of orthopaedics and diagnostics.

Drawing from lessons of the Fund's inaugural year, a lot of emphasis was placed on talking with clinical experts and establishing links between medical device companies and the NSW clinical base, and I believe this emphasis has resulted in highly clinically-relevant applications this year.

Again the task of assessing these high quality applications was not easy and I want to thank the wonderful members of the Expert Panel – Neville Mitchell, Dr Bob Frater, Michael Still and Adam Spencer, and I welcome and thank new member Dr Greg Keogh. I also wish to thank the sub-committee which assisted with the shortlisting and the MDF Secretariat led by Dr Tony Penna.

But most of all I congratulate the recipients of the Medical Devices Fund for 2014 whose innovative and inspiring work will, without question, have lasting and meaningful impacts on the health system and the community.

Mary O'Kane NSW Chief Scientist & Engineer

Allegra Orthopaedics Limited









Allegra Orthopaedics ("Allegra") is commercialising a synthetic "load bearing" bone graft medical device, which in one product, presents highly sought after physical, mechanical and biocompatible properties which are currently not being met in the orthopaedics.

The medical device is a bio-ceramic scaffold with outstanding potential for supporting bone regeneration in load bearing applications. Preliminary studies indicate that it duplicates the mechanical strength, elasticity and bioactivity of bone grafts without the many recognised disadvantages of these current surgical practices; be they autograft (using patient's own bone), allograft (same species' bone), xenograft (different species' bone) or metal implants.

The emergence of synthetic bone substitute materials, with and without biological bone growth factors has been increasing in orthopaedic surgery, however their use has been restricted to fillers or for use in non-load bearing applications.

Allegra's synthetic bone substitute, Sr-HT-Gahnite has the potential to be the first commercialised synthetic bone substitute platform of products suitable for building bone in large bone defects under load.

Allegra's technology has been developed by Professor Hala Zreiqat and her team from the Tissue Engineering and Biomaterials Unit, Faculty of Engineering and Information Technologies, University of Sydney. Allegra has licensed the exclusive rights from the University of Sydney to the late stage patent applications which cover the formulation, production techniques and application of this breakthrough material.

Bone Substitute Material

Sr-HT-Gahnite presents a major advance in synthetic materials by combining a highly porous and interconnected scaffold with outstanding mechanical and bioactive properties for regenerating large bone defects under load. There is no perceived restriction for the product as it has the potential for use in non-load bearing as well as load bearing applications in all ages.

There are no synthetic alternatives to Sr-HT-Gahnite as all options are indicated for nonstructurally integral uses. The current practice to address load bearing implants is through either metal only, with slow to no bone integration, or through autogenic and allogeneic implants with their inherent disadvantages.

Bone graft products are used in a wide range of orthopaedic surgery applications; fusing joints to prevent movement in the spine and/or extremities; repair injured bone/joints; accelerating repair of fractures with bone loss, or simply repair bone voids from surgery, trauma, removal of bone tumour, disease and/or infection.

The clinical relevance of Sr HT-Gahnite's potential include reduced morbidity associated with a second surgical procedure, reduced infection risk, reduced medication and based on the preclinical evidence to date, there is the potential for more rapid bone growth leading to improved patient recovery rates.

Allegra is a publicly listed company on the ASX and its sales, design and manufacturing team is based in St Leonards at its 2,000m² manufacturing facility. "The NSW Medical Devices Fund is focused on the translation of research into commercial products. The winning enterprises are all fine examples of research that has true commercial potential and the ability to contribute to the development of the medical device industry in New South Wales."

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Neville Mitchell NSW Medical Devices Fund Panel Member



Public/Private Company		Public ASX: AMT
Stage/Category	Pre-c with	linical medical devices orthopaedic revenues
Website	www.all	egraorthopaedics.com
Contact		Tom Milicevic, CEO
	all	Email: tom.milicevic@ egraorthopaedics.com
	Pł	none: +61 402 304 015

Kico Knee Innovation Company Pty Ltd





Kico Knee Innovation Company provides orthopaedic surgeons with state of the art dynamic, functional and patient specific planning and simulation solutions. The technology is currently focused for application on total hip and knee arthroplasty.

Using engineering techniques derived from aerospace and automotive industries, our software provides dynamic information about an individual's joint performance in more depth than ever before.

Over 2,000 patients have already been analysed. In August a new milestone was achieved with 100 cases being simulated prior to surgery. Substantial clinical interest has developed around the world. In Australia, significant commercial progress has been made with our hip partner Corin and our knee partner Global Orthopaedic technology.

Global Scale



"The wide range of excellent applications we see shows us that Medical Device innovation is alive and well in NSW."

Dr Bob Frater NSW Medical Devices Fund Panel Member

"Again, this year, there was a very strong field of contenders. Each medical device submitted has the potential to make a significant difference to health outcomes. Choosing those to be awarded funding was, therefore, very challenging however, I am excited to be able to support this year's winners in the development of their ideas under Minister Skinner's Medical Device Fund initiative. I wish them every success."

Michael Still NSW Medical Devices Fund Panel Member





Public/Private Compa	ny Private
Stage/Category	Early stage commercialisation
Website	www.optimizedortho.com
Contact	Bede O'Connor

The Sydney Children's <u>Hospitals Ne</u>twork







The Kids Research Institute is a leading translation research centre for children, embedded in the Sydney Children's Hospitals Network (SCHN) and located at The Children's Hospital at Westmead. Our translational research provides patients and families early access to new and innovative treatments and improves the quality and efficiency of our clinical services.

The Orthopaedic Research and Biotechnology Unit, led by Professor David Little at the SCHN is focussed on advancing orthopaedic care through an improved understanding of bone diseases, advancing bone healing and development of orthopaedic implants. A pipeline of novel implantable devices is currently being developed.

"It has been a privilege to have been invited to participate in the Expert Panel of the Medical Devices Fund. It is clear that there are a large number of local researchers and companies developing improvements in technology to benefit the people of New South Wales. I have found the concept exciting and challenging, and would welcome the chance to contribute to this important initiative in the future."

Dr Greg Keogh NSW Medical Devices Fund Panel Member



Paediatric Bone Rod

The SCHN is commercialising a revolutionary paediatric implant (SyMaxys) to treat children born with brittle bones or malformed legs. The technology, which was developed by Professor David Little and Dr Justin Bobin, addresses an unmet clinical need for fixation devices which grow with the child's bone. The SyMaxys technology provides constant stability and support to the limb necessary for correcting the disorder, while accommodating bone growth. The novel design extends the life of the device and minimises the need for invasive replacement surgery.

The underlying technology is subject to patent applications, and will be applied to other conditions such as spinal disorders where both stability and movement are equally important.

The SCHN is currently negotiating a licence agreement with a leading orthopaedics device company to complete the development and commercialisation of the device. Professor Little and his team will complete the development and testing of the SyMaxys device in NSW before seeking regulatory approval to start applying it in patients. They anticipate having the device available within three years, with the SCHN being the first to offer this device to its hospitals – Sydney Children's Hospital, Randwick and The Children's Hospital at Westmead.



Public/Priv	Public/Private Company n	
Stage/Cat	gory n/a	
Website	www.schn.health.nsw.gov.au/ www.kidsresearch.org.au/	
Contact	Professor David Little	
	Paediatric Orthopaedic Surgeon, The Children's Hospital at Westmead	
	Head of Orthopaedic Research and Biotechnology Unit, SCHN	
	Professor of Paediatrics & Child Health	

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SpeeDx Pty Ltd





SpeeDx is a medical diagnostic company focused on developing and commercialising clinical tests based on their patented, ground breaking DNA analytical technologies. Their innovative chemistries have a superior capacity to detect multiple clinically relevant genetic biomarkers in patient specimens. This provides a platform for developing a wide range of diagnostic tests based on detecting the genetic "bar-code" of disease-causing bacterium or viruses, or of human genes associated with cancers and other diseases.

SpeeDx has created a successful business based on licensing its inventions which are protected by an extensive patent portfolio. Their licensees market and develop products for clinical research and human diagnostics. For example, Bioline Australia has been licensed to sell kits to hospitals and private pathology laboratories for assessing efficiency of genetic testing procedures. These kits are widely used within Australia and are now being launched internationally. Another licensee, Biocartis NV a European reagent and instrument manufacturer, anticipates launching a "companion diagnostic" using SpeeDx' technology in early 2015. This product will allow oncologists to tailor therapy for patients by measuring features of their cancer. This information allows the prescription of the drug(s) most likely to be effective in treating the cancer. The product analyses more cancer mutations in a single reaction than competitors' kits, and is more sensitive.

In vitro diagnostic test for detection of viruses and bacteria causing meningitis

Capital generated from SpeeDx' early licencing and co-development activities has funded internal development of a pipeline of diagnostic products, in line with the company's longer term goals. The most advanced is a test to detect eight bacteria and viruses known to cause meningitis in children and adults. This will provide a tool to identify the pathogen and aid rapid diagnosis of this potentially life threatening disease. Other products are in earlier stage development. SpeeDx' initial tests will run on instruments already in routine use in pathology laboratories so that adoption will not require investment in new equipment or additional staff training.

The company is also working on next generation "point of care" solutions, aimed at moving testing out of laboratories and to the patients' location. The team sees this as an area where significant value can be added, particularly in critical care and/or rural settings where access to equipment may be limited.

SpeeDx has a strong track record of developing and commercialising novel technology applicable to medical diagnostics. Inspiration for invention comes from staff at all levels of this innovative, dedicated team including graduate students enrolled through the University of NSW. The company strives to make an impact on human health both locally and globally.





"The 2014 panel process has shown once again that great ideas and tenacity are thriving in the NSW Medical community."

Adam Spencer NSW Medical Devices Fund Panel Member



Medical Devices Fund Expert Panel



Professor Mary O'Kane

Professor Mary O'Kane is the NSW Chief Scientist and Engineer and also a company director and Executive Chairman of Mary O'Kane & Associates Pty Ltd, a Sydneybased consulting practice.

She is also Chair of the Development Gateway and Development Gateway International, Chair of the CRC for Spatial Information, and a director of NICTA, Capital Markets CRC, PSMA Ltd, Business Events Sydney, and KUTh Ltd.

Professor O'Kane was Vice-Chancellor of the University of Adelaide from 1996-2001. She is a former Chair of the board of the Australian Centre for Renewable Energy, a former member of the Commonwealth's Review of the National Innovation System, Australian Research Council and the Co-operative Research Centres (CRC) Committee, the board of FH Faulding & Co Ltd and the board of CSIRO. She is a Fellow of the Academy of Technological Sciences and

Engineering and a Fellow of

Engineers Australia.



Mr Neville Mitchell

Neville is Chief Financial Officer and Company Secretary at Cochlear Limited (1995 – present). His responsibilities include;

- Part of Senior Management Team charged with the setting of Cochlear's global strategic development and its implementation.
- Responsible for financial management for Cochlear Limited world-wide including revenue, working capital control and disclosure reporting.
- Principal role in evaluation and subsequent acquisitions by Cochlear Limited.
- Risk Management and Treasury functions including FX strategy and execution.
- Company Secretarial duties including ASX and statutory requirements in Australia and overseas. Attendance at all Cochlear Limited Board meetings with direct input on financial and operational matters, also attendance and participation at all Board Committee meetings.
- Investor Relations management including formulation and execution of IR strategy for Cochlear Limited. This includes direct contact with fund managers / investors, analysts and financial press in Australia and abroad.
- Government Relations strategy and relationships.



Dr Bob Frater AO

Dr Bob Frater AO is one of Australia's most respected scientists. He has researched electronics, telecommunications, radioastronomy instrumentation, electro-acoustics and biomedical devices. In 1996, he was made an Officer of the Order of Australia for his contributions to science in Australia and internationally.

His career went from industry (AWA, OTC, Ducon) to academia (Electrical Engineering at Sydney University), then to CSIRO from Chief of Radiophysics Division to Deputy Chief Executive, and now ResMed as VP Innovation. He also serves as Chief Technology Officer for Innovation Capital and is a member of a number of advisory committees.

His CSIRO achievements included construction of the highly successful \$50 million Australia Telescope at Narrabri and sponsorship of the WLAN developments by his former students from University of Sydney. He is a Fellow of the Australian Academy of Science and a Fellow of the Australian Academy of Technological Sciences & Engineering.



Mr Michael Still

Mr Still has enjoyed a 30 year career in investment banking, corporate finance and infrastructure markets both in Australia and abroad. He is head of the Infrastructure business of Investec Bank (Australia), a global specialist bank and asset manager. He has held CEO and senior roles with significant organisations, most recently with Alba Capital Partners Limited, a specialist originator and financier of infrastructure. He has long experience in global capital raising and structuring, corporate advice, PPPs and the delivery of infrastructure and projects. He holds a Master of Business Administration from MGSM.

His previous employment include; Managing Director, Capital Solutions, Baulderstone Hornibrook (construction organisation, 2003-2007), Company Directorships and Corporate Advisory (2001-2003), Managing Director, Triden Corporation Ltd (construction company, 1998-2000), Managing Director, Altair Financial Group (private investment banking firm, 1989-1998), Executive Director, McClintock Associated Ltd (investment banking firm, 1985-1998), Manager, Corporate Finance and Advisory, Trans City Ltd (investment bank, 1982-1985).



Mr Adam Spencer

Adam Spencer began his career in radio by winning the Triple J Raw Comedy championship in 1996. From there, Adam became a casual presenter, and eventually took over the coveted TRIPLE J breakfast time slot, co hosting with Wil Anderson from 1999 - 2004. A consummate learner, Adam holds a first class honors dearee in Pure Mathematics and has an immense interest in science. From 2006 -2013 Adam presented the highly coveted breakfast show for ABC 702.

Adam's other outstanding achievements include being voted "Best Speaker in the World" at the World University Debating Championships. Prior to this, Adam was captain of the Australian Debating Team for 3 years. He was winner of the National Championships and winner of the Australian University Championships.

Adam has had extensive experience on various boards and authorities; he continues to serve on the Senate of the University of Sydney, the NSW Premier's Advisory Committee on Greenhouse and Global Warming and the NSW Health Department's Clinical Ethics Review Committee as well as being an ambassador for the Fred Hollows Foundation, helping out with numerous charities and speaks regularly at science and maths conferences Australia wide.



Dr Greg Keogh

Dr Keogh is a Senior Staff Specialist Surgeon at Sydney's Prince of Wales Hospital, and a Fellow of the Royal Australasian College of Surgeons (FRACS). His clinical interests include the management and treatment of gastrointestinal cancer, particularly in the upper gastro-intestinal tract.

He is currently surgical director of the Prince of Wales Hospital Operating Theatres. He also currently fills the role of Clinical Stream Director for Surgery, Anaesthetics and Peri-operative Medicine for the South East Sydney Area Health Service.

His other roles include National Director of the CPMEC Australian Curriculum Framework for Junior Doctors Project, and a senior medical adviser to HETI (Health Education Training Institute). He is a member of the NSW Surgical Services Taskforce, and the NSW Acute Care Taskforce.

He has been a former Director of Clinical Training at the Prince of Wales Hospital, chair of the Postgraduate Medical Council of NSW and state director of basic skills courses for RACS.

Notes

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MEDICAL DEVICES FUND

Health and medical research play a vital role in the continued growth and better health of our community and economy. From increased life expectancy and new treatments for disease, and technologies that change the way we live and work, to addressing environmental challenges scientific research and the knowledge it generates affects us all.

The Office for Health and Medical Research (OHMR) plays a crucial role in supporting the State's leading health and medical research efforts. OHMR helps support the broad range of outstanding health and medical research effort being carried out in NSW.

OHMR works with the health and medical research communities, the higher education sector and business to promote growth and innovation in research to achieve better health and environmental and economic outcomes for the people of NSW.

OFFICE FOR HEALTH AND MEDICAL RESEARCH

The NSW Health and Medical Research Strategic Review recommended that NSW be enabled to contribute to the discovery and application of new treatments and diagnostic techniques and devices that will be major contributors to health reform into the future. The NSW Government established the Medical Devices Fund (MDF) to help encourage and support investment in the development and commercialisation of medical devices and related technologies in NSW.

The key objective of the MDF is to promote new and innovative medical devices and technologies within NSW that may have a global benefit. Broadly, the MDF aims to:

- provide support to individuals, companies, public and private hospitals, medical research institutes, universities, other public sector research organisations, and the medical devices industry, to take local innovation to market; and
- increase the uptake of NSW medical devices by the health system where they are cost effective and contribute to improved patient outcomes.