

# Medical Devices Fund

# 2013







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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SHPN: (OHMR) 130209 ISBN: 978-1-74187-838-7

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## Contents

A Message from the Minister	2
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A Message from the Chair	3
Elastagen Pty Ltd	4
Endoluminal Sciences	6
HEARworks Pty Limited	8
MobiLife Pty Ltd	10
Saluda Medical	12
Medical Devices Fund Expert Panel	14
Notes	16



#### A Message from the Minister

July 2013

#### The establishment of the Medical Devices Fund was a key election commitment for the NSW Government and reflects our support for medical research in this state.

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.

NSW Ministry of Health is committed to establishing a global reputation as a resilient, innovative Centre of Excellence for health and medical research. A high-quality health system that is responsive to scientific advances and generates health, social and economic benefits for the people of our state is instrumental in creating this status.

The NSW Government has committed \$5 million annually for a new Medical Devices Fund 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. In its inaugural year, the NSW Government boosted the funds to make \$8 million available.

New South Wales encompasses a founding profile in medical device technology and is leading the way in Australia's development to commercialising international market breakthroughs. Investing in local technologies provides many benefits to the NSW population through better health care and practice, paving a brighter future for generations to come.

As Minister for Health and Minister for Medical Research, I am passionate about research and ensuring that it is translated into better health outcomes for the people of this state. It is encouraging to recognise the high quality research and practical developments taking place within our universities and publically funded organisations as they create pathways for NSW clinicians, scientists and engineers to practice and advance technologies in NSW.

The recipients of the Medical Devices Fund will be pivotal contributors to building future medical technology commercial success in NSW.

I offer my most sincere thanks to Professor Mary O'Kane, NSW Chief Scientist and Engineer, the members of her Assessment Panel and the support staff in the Ministry who provided outstanding leadership in the foundational year of the Medical Devices Fund. To the hundreds of individuals and organisations who submitted applications, I thank you for your innovative ideas and providing hope for future medical breakthroughs in NSW.

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Hon Jillian Skinner MP Minister for Health Minister for Medical Research

2





#### A Message from the Chair

July 2013

The Medical Devices Fund is an initiative championed by the Minister for Health and Minister for Medical Research, which draws inspiration from groundbreaking medical device companies like Cochlear and ResMed. Noting that, the Panel came together with great enthusiasm for the task of assessing applications.

We were, however, genuinely surprised by the number and quality of applications for the Medical Devices Fund.

It was also impressive to see the range of areas across the health system that these devices aimed to support: chronic pain management, hearing, skin repair, home-based IV and sealing technology to name a few.

There are some lessons we can learn from the inaugural round, including that we need to develop better links between medical device companies and the excellent clinical base in NSW, but overall it is pleasing to see such an enthusiastic first start.

The selection task was a tough one but I was lucky to be supported by the members of the Expert Panel – Neville Mitchell, Dr Bob Frater AO, Michael Still and Adam Spencer – whose insight, expertise and good humour were greatly appreciated. I'd also like to thank the sub-committee which assisted with the short-listing of the applications and the MDF Secretariat led by Dr Tony Penna.

Most importantly, I offer my congratulations to the recipients of the Medical Devices Fund whose hard work and innovation have the potential to make a meaningful contribution, not just to improving our health system, but to the health and happiness of the community.

Mary O'Kane NSW Chief Scientist & Engineer

#### Elastagen Pty Ltd









#### Elastagen is a clinical stage medical device company that is pioneering elastatherapy™ using the human protein elastin to naturally repair the skin.

Elastin is a critical component of the skin, being present as fibres which confer unique physical properties to skin tissue. Elastin enables the skin to endure constant stress, especially in areas requiring repeated stretch and recoil such as at the joints. Elastin also plays a critical role during the wound healing process where it contributes to reduced wound contraction and improved skin tissue regeneration.

Elastagen's technology has been developed over the past twenty years by Professor Anthony Weiss and his Elastin Laboratory at the University of Sydney. Elastagen has acquired exclusive rights from the University of Sydney to a broad patent portfolio which covers the production, formulation and application of this unique biomaterial.

"This has been a fascinating process - the breadth and quality of ideas has made our job like that which should be said of any adjudication panel... damn difficult! I hope our efforts have assisted these passionate, intelligent, tenacious researchers bring their ideas to fruition"

Adam Spencer Medical Devices Fund Panel Member



#### Elastatherapy<sup>™</sup> Skin Repair

Elastagen is the first company globally to have succeeded in the scalable, commercial, clinical grade manufacture of the full length recombinant human elastin protein. In addition, the company has completed a broad range of preclinical and clinical studies and successfully demonstrated the potential of its elastin biomaterials to assist in skin repair and regeneration.

A major focus for the elastin technology is on the medical repair and regeneration of the skin. For example, following recovery from burn injuries, patients will often have severe scarring which requires surgical revision due to discomfort and a lack of skin mobility. The surgical revision involves the removal of the scar tissue and replacement with a skin template to encourage the growth of a more natural skin.

Elastagen has worked closely with Prof Weiss at the University of Sydney and leading burns surgeons to demonstrate that elastin has the potential to improve the performance of the skin template.

The inclusion of elastin may enable both a reduction in the required number of surgical interventions and result in a significant improvement in the quality and physical properties of the repaired skin. The company is now planning to undertake further clinical studies of this promising technology prior to seeking regulatory approval of the product.

Elastagen is located in Sydney, Australia, and is a venture backed private company.





Listed/Private Company	Private
Stage/Category	Clinical Stage/Medical Device
Website	www.elastagen.com
Contact	Robert Daniels, CEO
	Email: r.daniels@elastagen.com
	Phone: +61 424 439 481

## Endoluminal Sciences





#### Endoluminal Sciences is developing a breakthrough technology for the treatment of failing heart valves.

While minimally invasive techniques to insert heart valves are a significant improvement over open heart surgery, there is a major limitation with the therapy:

Critical leakage from around these valves inserted by the less invasive catheter technique occurs in up to 50 per cent of patients.<sup>1</sup> As a result of this complication, some of the blood pumped into the aorta leaks back into the heart, weakening it and eventually leading to heart failure.

Endoluminal Sciences' solution is a novel sealantbased medical device that uses a combination of state-of-the-art mechanical engineering and polymer science to overcome the life-threatening failure mode of leakage from around the sides of minimally invasive heart valve implants. The technology addresses the problem of leakage in a manner superior to any device currently in clinical trials or on the market anywhere in the world.

The innovation is geared towards dramatically improving medical outcomes and safety for patients while at the same time significantly improving ease-of-use for the physician and reducing the financial cost to the health system.

The technology has received several accolades internationally including being recognised as the top five new technologies in structural heart disease at the world's largest conference in Interventional Cardiology Medicine, Transcatheter Cardiovascular Therapeutics.

<sup>1</sup> N Engl J Med 2012; 366:1686-1695

#### Sealing Technology for Minimally Invasive Heart Valve Replacement

The leadership team of Endoluminal Sciences constitutes a pioneering profile in global medical device technology development and commercialisation. Endoluminal Sciences is further supported by a global network of clinical practitioners and researchers considered key opinion leaders in the fields of interventional cardiology, cardiovascular and vascular surgery.

Currently, the problem of leakage limits the extension of benefits of minimally invasive heart valve replacement to patients that are currently offered open heart surgery. Endoluminal Sciences' technology has the potential to enable practically all patients with failing heart valves to be treated by a minimally invasive technique – making open heart valve surgery a thing of the past.

Endoluminal Sciences' immediate focus is the minimally invasive treatment of aortic valve stenosis (disease causing narrowing of the aortic valve) and mitral valve regurgitation (disease causing leakage of the mitral valve) – common conditions that together constitute the vast majority of serious heart valve disease affecting the population. The intellectual property portfolio developed by Endoluminal Sciences also has direct applicability for treatment of a much broader range of vascular and structural heart disease states, including the treatment of pulmonic and tricuspid valve disease, and the treatment of abdominal and thoracic aortic aneurysms. "The Medical Devices Fund is a forward thinking initiative for the home state of Cochlear and ResMed, key Australian medical device companies."

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Dr Bob Frater AO Medical Devices Fund Panel Member



Listed/Priv	ate Company	Private
Stage/Cate	egory	Early Stage/
	Medical Device Techno	ology/Cardiovascular
Website	www.endc	luminalsciences.com
Contact		Ashish Mitra, CEO
	Email: amitra@endc	luminalsciences.com
	Pho	one: +61 421 509 033

#### HEARworks Pty Limited









HEARworks Pty Limited is the commercial arm of the The HEARing CRC and works in concert with that organisation for the common purpose of creating sound value<sup>™</sup> through research and innovation to prevent, and to better remediate, lost productivity resulting from hearing loss in children and adults.

HEARLab is an innovation of the HEARing CRC and National Acoustics Laboratories, developed to meet the needs of clinicians for a portable, multifunctional instrument to conduct electrophysiology for the assessment of hearing. HEARLab comprises basic hardware that is driven by software modules running on a standard laptop computer.

"The Medical Devices Fund initiative attracted applications from a wide range of quality and innovative start up companies in NSW. The successful applicants all have the potential to make a real positive contribution to improved health outcomes for patients. Importantly the MDF provides the incentive for the commercial development of these businesses to remain focused in NSW"

*Neville Mitchell Medical Devices Fund Panel Member* 



#### Development of a Novel Fully Automatic Cortical Audiometer

The first two HEARLab modules are for Aided Cortical Assessment and Auditory Brainstem Response testing respectively. These modules were developed with funding support from the Commonwealth, AusIndustry and the NSW Government.

The Medical Devices Fund grant will help to fund the development of the third HEARLab module – the Automated Cortical Assessment test.

This critical new piece of software will provide the world's first fully automated and totally objective test of hearing thresholds.

The test will safely and painlessly measure signals generated by the auditory cortex of the brain in response to sound, while not requiring any active cooperation from the patient. The test will be fully automated, which will both decrease the time needed to perform the test, and also decrease the skill level needed to administer the test.

There is a need for this test at both ends of life.

Firstly, it will enable the testing of awake babies and older children with multiple disabilities, even those with auditory neuropathy (a form of deafness that cannot currently be objectively assessed in any other way).

Secondly, it will enable the testing of elderly people who cannot respond behaviourally, typically because of stroke or dementia. The new test will therefore fill a gap in the tests available to clinicians who work with babies and elderly people with cognitive impairment. It will also have application in testing hearing to verify hearing loss in those seeking compensation for occupational noise injury.

HEARLab and the Automated Cortical Assessment test will be welcomed around the world, but the inclusion of Australian Hearing within the Hearing CRC will ensure that it is immediately available to the people of NSW. In addition, the initial trials with the new module will occur here, at the Australian Hearing Hub in Sydney.





y Private
Growth Stage/
Biotechnology Commercialisation
www.hearworks.com.au
A/Prof Robert Cowan
Email: rcowan@hearingcrc.org
<b>Phone:</b> (03) 9035 5347

9

## MobiLife Pty Ltd





MobiLIFE is a joint venture company established by medical device executives and the University of Newcastle (UoN) to deliver ideas and concepts into the medical device marketplace. Since its inception in 2002 the company has grown in strength with an exceptional team of individuals with a background of delivering results in the medical device sector.

MobiLIFE is nearing the commercialisation stage of its first project, which is aimed at significantly improving the choice and quality of treatment options available to medical professionals for the care of patients outside of hospital i.e. home care based treatments.

The mobiLIFE home care project is based on the mobiDRIP; an innovative new portable intravenous (IV) pump developed by researchers at UoN. The history of the project is that a conversation over coffee resulted in a radically new conceptual design being sketched on a napkin!

"The Medical Devices Fund has been an invigorating exercise, seeing and listening to a team of scientists, clinicians, industry and entrepreneurs articulate how ideas are translated into practical and novel solutions to clinical or diagnostic issues"

Dr Antonio Penna Director, Office for Health and Medical Research



### mobiDRIP: Improving Patient Outcomes and Reducing Health Care Costs

The mobiDRIP is a unique, new, low cost, high accuracy, mechanical infusion device; the first hybrid device to combine the accuracy of an electronic pump with the low price tag of a disposable pump.

This new infusion pump, which is revolutionary in its simplicity, reduces costs and improves patient care.

The mobiDRIP has been ergonomically optimised and can be worn discreetly by a mobile patient whilst aiding recovery by intravenously delivering continual dosages of medical fluids such as antibiotics, pain relief, chemotherapy and nutrition.

The device provides greater choice for nursing staff and facilitates more rapid hospital patient discharge; resulting in considerable cost savings for the health care system and better outcomes for patients.

The future outlook for mobiLIFE is very exciting. The company has already established a Therapeutic Goods Administration approved clean room and rapid response drug compounding service that utilises the latest facility design to provide the high service levels demanded by the market. This new Good Manufacturing Practice licence approved facility provides for the filling and delivery of mobiDRIPs to NSW, QLD and beyond.

MobiLife's next focus is to utilise the product refinement, reference sites and revenue stream created by the successful domestic commercialisation of the mobiDRIP device and service, to support the insertion of the mobiDRIP device into the globally significant home care markets.





Listed/Private Company		Private
Stage/Cate	gory	Early Stage,
	Medical Device & Pha	rmaceutical Services
Website	www.	mobilifemedical.com
Contact	Prof P	aul Dastoor, Director
	Email: Paul.Dasto	or@newcastle.edu.au
	PI	none: (02) 4921 5426

## Saluda Medical









Saluda Medical is a Sydney based start-up company developing a groundbreaking new implantable device for the treatment of chronic neuropathic pain. The company was spun out of National ICT Australia, Australia's leading ICT research establishment in early 2013 to commercialise a range of neurostimulation technology developed there over 4 years.

"As a personal mission the New South Wales Minister for Health and, importantly, Medical Research, has brought vibrancy and new vitality to Medical Devices research with the launch of the Medical Devices Fund. Accelerated development of medical devices is key to the ongoing improvement of peoples' health and economic advancement.

The clinical, engineering, commercial, intellectual property and economic aspects of each applicant and their device was rigorous and so the devices which the Minister has agreed to support are assured of the best chance of success in improving the lives and health of the people of New South Wales and become global commercial successes. I am very pleased to participate in this very exciting initiative."

*Michael Still* Medical Devices Fund Panel Member

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## **Closed Loop Spinal Cord Stimulation** for Chronic Pain

Using a world's first neural recording technology, the company will initially focus on developing a closed-loop feedback spinal cord stimulation device.

The neural recording technology makes it possible to measure the minute electrical responses from nerves immediately after they have been stimulated. Existing devices cannot make this measurement and so rely on manual intervention to establish an optimal level and location. Once commercialised, experts believe this technology will make its way into every neuromodulation device implanted in a human, be it for spinal cord stimulation, deep brain stimulation or other treatments comprising a global market worth \$3 billion per annum.

Spinal Cord Stimulation is a treatment for chronic neuropathic pain where the electrical stimulation replaces the pain with a buzzing or tingling feeling in the area of the pain. Current products suffer the major problem that as the patient changes posture, the spinal cord moves relative to the electrode causing the level of stimulation of the nerves to change. This variability causes many patients severe discomfort leading some to elect not to have a permanent implant while others set stimulation levels below the optimum. It also results in patients needing to continuously manually adjust the level of stimulation. Closed-loop feedback control of stimulation allows for the automatic setting of an optimal level of stimulation.

The company has already trialled its technology on human subjects in acute settings using a prototype externalised stimulator. Results so far indicate that a device using closed-loop feedback controlled stimulation provides improved pain relief, more of the time, without unpleasant side effects or the need for continuous manual readjustment by the patient.

These results have been presented at key US and European scientific conferences in the field to the acclaim of leading neuromodulation surgeons and academics.

Saluda Medical is now in the process of engineering an implantable device and conducting clinical trials to support regulatory approval of the device to commence sales in 2016.





Listed/Private Company	y Private
Stage/Category	Commercialisation Stage
	Neuromodulation
Website	www.saludamedical.com
Contact	Dr John Parker
Email	; john.parker@saludamedical.com
	Phone: (02) 9376 2125

#### **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 degree in Pure Mathematics and has an immense interest in science. These passions lead Adam to hosting the ABC program QUANTUM and FAQ from 1998 to 2001. Prior to this Adam was a regular guest on Channel Ten's GOOD NEWS WEEK series, ABC's THE FAT and continued to be a regular guest on THE GLASSHOUSE. In 2003 Adam hosted HIT & RUN for the Foxtel's Comedy Channel and in 2005 Adam hosted JOKER POKER for Freehand Group which screened on Channel Ten. Adam returned to radio in 2006 where he still presents 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 was a regular performer at Belvoir Street Theatre's 'Theatresports' and speaks regularly at science and maths conferences Australia wide.

Adam's book LITTLE BOOK OF NUMBERS has been published by Penguin and has been translated into many languages around the world.

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 and helping out with numerous charities.

## Notes


#### 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.