

**Portfolio of  
Technology Investment  
Briefs**

**NSW  
AREA HEALTH  
SERVICES**

**Office of  
Commercialisation**

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**NSW  HEALTH**

**Office of Commercialisation**

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# **A. Devices**

# 1. Integrated System for Precision Ablation of Tissue

## Summary

A group of patented technologies which substantially improve radiofrequency (RF) ablation procedures. Technology has been developed by a group of leading interventional cardiologists/electrophysiologists.

### 1.1 Intramural Needle Tipped RF Ablation Device

#### Summary

Describes an intramural needle tipped catheter for RF ablation so that good-sized intramural or sub-epicardial lesions can be created by endocardial catheter techniques.

### 1.2 Intraoperative Endocardial and Epicardial Ablation Probe

#### Summary

Describes an elongate, malleable ablation probe and body consisting of a number of longitudinally spaced electrodes separated from one another by insulating material. These electrodes are substantially flat.

## The Technology

Over many years our clinical research team has developed various components for an integrated system for RF ablation of tissue. We hold patents for 4 distinct components necessary for effective RF ablation of cardiac tissue as well as other tissue. With a main focus in treatment of atrial fibrillation (AF), our RF ablation patents cover a system for simultaneous unipolar multi-electrode ablation using an “RF splitter” which individually adjusts power according to the temperature at each electrode, multipolar transmural needles for intramural ablation at surgery for a wide variety of arrhythmias and creation of long lesions with our malleable intraoperative endocardial and epicardial ablation probe using flat electrodes for better tissue contact. We also hold patents on a catheter intramural needle delivery system for intramural RF ablation.

## Applications

This system can be applied for electro surgery, particularly Radio-Frequency (RF) ablation in Cardiology/Cardiac surgery and General surgery.

## Market

Since 1989, radiofrequency (RF) ablation procedures have increased dramatically. The market for ablation continues to expand, as indicated by the more than 2-fold increase in hospitalizations for atrial fibrillation over the last decade. Today, over 100,000 RF ablation procedures are performed annually in the US alone.

In 2003, more than 154.7 million electrocardiography, endovascular, non-invasive diagnostic imaging, and near patient in vitro testing procedures were performed in the US to diagnose cardiovascular diseases/disorders. These procedures generated approximately \$3.6 billion in corresponding product sales, with non-invasive diagnostic imaging systems

sales accounting for 45.8% of the total, imaging contrast agents and biopharmaceuticals sales for 21.9%, transcatheter diagnostic systems sales for 17.4%, near patient in vitro testing products sales for 7.9%, and electrocardiography systems sales for 7.0%. Growing at a compound annual rate of 8.0%, sales of these products are expected to reach an estimated \$4.8 billion in the year 2007.

## IP Position

Sydney West Area Health Service (SWAHS) holds National Phase patents in Australia and the US for the "RF Splitter"; Australia, US, and Europe for both the Multipolar Transmural Probe and the Intraoperative Endocardial and Epicardial Ablation Probe; and a PCT for the catheter Needle-Tipped Surgical Device.

## Commercialisation

SWAHS is seeking a partner to license our technology for the manufacture, distribution, and sale of any of the RF ablation components. The licensee may fast-track regulatory approvals through clinical trials at Westmead Hospital with our clinical professionals. The potential licensee may also be able to combine their existing products with SWAHS patents and exploit access the RF-ablation market in the US.

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## 2. Microwave Medical Ablation (MMA) Technology

### Summary

Minimally invasive tissue ablation system – devices and software – for electrophysiology (EP) ablation, delivering deeper, continuously linear ablation lesions to the tissue than alternative Radiofrequency (RF) ablation, whilst avoiding contact with the tissue.

Professor David Ross, Specialist Cardiologist, in conjunction with Dr Ananda Sanagavarapu, Faculty Engineering, UTS and their teams have worked on the development of the system and proof of concept testing. The technology is patented.

### Market

Heart rhythm disorders or arrhythmias are very common and are believed to cause 500,000 deaths per year in the USA alone.

### Benefits

This technology provides for a significantly improved means of reducing arrhythmias in a more reliable and safer way than existing technologies. These disorders are commonly treated with medications which have a low success rate.

### Technology Investment Brief

**Industry:** Medical Technology  
**Proposed Business:** Development of a microwave ablation system to treat cardiac arrhythmias.

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## Microwave Antenna for Medical Ablation (MAMA)

### *Business Description*

A minimally invasive microwave antenna for medical ablation (MAMA) system which we have developed in the cardiac sphere that delivers greater control to the EP/Cardiologist by targeting the cardiac arrhythmia with deeper, continuously linear ablation, whilst avoiding tissue contact. It can also be used in other spheres.

### *Value Proposition*

Current pharmaceutical treatments for arrhythmias have a success rate of ~50%. Whilst current ablation techniques are less invasive than open-heart surgery, side effects such as burning of tissue, and limited efficacy (lesions too broad or too focused on one point) leave open-heart surgery as the only viable alternative. The MAMA system overcomes the limitations of RF ablation and allows for use with standard catheter sheaths inserted via the femoral vein, enabling minimally invasive treatment.

### *Potential Market Applications of the Technology*

Each year, millions of people are affected by heart rhythm disorders worldwide. Arrhythmia claims more than 500,000 lives every year in the USA. Atrial fibrillation (AF), the most common form of arrhythmia, occurs in up to 1% of western populations. MAMA will initially target the cardiac arrhythmia patients with AF. In the USA alone, the cardiac catheter ablation market is valued at \$6B, and as the western population ages, the number of arrhythmia patients will increase dramatically. Potential additional applications of the technology include soft tissue ablation (for example liver, endometrium and brain), and treating malignant tumors.

### *Competitors*

The MAMA technology would be competing with manufacturers of existing RF ablation systems such as Biosense Webster Inc (J&J), Boston Scientific, Medtronic, St Jude Medical. A smaller, more specialized competitor is Cardima Inc. Although the RF ablation market is dominated by these companies, none have the technological advantage, flexibility, and potential of our MAMA system.

## *Sustainable Advantage*

The team for the MAMA system comprises world-leading experts in two critical areas: Prof David Ross is a eminent interventional cardiologist specializing in cardiac ablation. Prof Ross has performed hundreds of cardiac ablations for AF, providing strong clinical expertise to the development of the technology. Dr Ananda Sanagavarapu is one of the foremost authorities in Australia on microwave antennas. The UTS Faculty of Engineering provides an excellent technical resource for the development of the MAMA system.

## *Status of Intellectual Property*

PCT AU04/000392 was filed 26/3/2004, with SWAHS and University of Technology, Sydney (UTS) as co-owners of the IP, with all due diligence and records properly documented and maintained. The Research team has been awarded more than US\$1M from the Australian Research Council (ARC), the National Health and Medical Research Council (NH&MRC), and Industry for development of the MAMA system. The team has conducted preliminary patent searches based on publicly available information. They believe that there are significant advantages to the MAMA system and that the technology does not infringe on other patents held by our competitors. Part of the proceeds from the initial funding would be used to secure and document the IP in the USA, Europe, and other strategic markets.

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## 3. Laryngoscope-Endoscope

### Summary

This technology offers a disposable and renewable laryngoscope-endoscope with unmatched light intensity, uniformity and distribution. It provides a unique ergonomically superior disposable oral-insert with unique power-handle and unmatched battery life. This technology revolutionizes an area which has not advanced in recent years.

Professor Peter Klineberg, Network Director Anaesthesia & Perioperative Medicine has developed the technology in conjunction with Techmin Pty Ltd, an Australian medical device company. Techmin are a fully compliant manufacturer of medical devices with an excellent reputation.

The first 1000 fully developed units are being made by Techmin for the purposes of formal clinical trials at Westmead Hospital. A number of prototypes have been developed as part of the development phase of this project.

### Market

In Australia the estimated market size is 80,000 units per year. Assuming similar patient management practices world-wide in developed countries, this equates to approximately 31.5 million intubations per year. A 10% market share is initially expected, equating to 3 million units per year. Although laryngoscopes are in standard use in hospitals across the world, there is a ground swell of demand for disposable laryngoscopes with improved visibility and utility.

### Benefits

It is a disposable single use device resulting in better infection control in hospitals and improved safety for patients and anaesthetists. Other benefits include:

- Better visibility from higher intensity, better-distributed light.
- Better intubation-blade profile which minimizes dental trauma.
- Cheaper by one-third (disposable portion) by comparison to another Australian disposable that has just entered the market. Australian-made by an Australian owned SME.

Instrumented handle allows simpler on-off activation, has vastly superior battery life and can double as a 'quick-assessment' torch.

### Costing

The Marketing Plan from Techmin details that the disposable blades will be sold ex-factory and through distributors. Chargers and handles will be sold via distributors and may be regarded by hospitals as a capital item in which case, price discounting (even below cost) can be considered to initially improve uptake.



More information at: [www.west-tech.com.au](http://www.west-tech.com.au) and [www.techmin.com.au](http://www.techmin.com.au)

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## 4. Heart Assist Technologies Pty Ltd

### Summary

This is an implantable cardiac device to boost the capacity of the heart using a direct compression technology which takes a unique approach over other mechanical heart assist devices.

It has undergone significant development to the proof of concept stage, and prototypes have been demonstrated and used in sheep with a high success rate.

The device has been widely recognized and has received prizes and awards.

This technology has been developed by leading-edge interventional cardiologists based at the Cardiac Technology Centre at Sydney's Royal North Shore Hospital.

### Advantages

Support heart and improve circulation without blood contact  
Rapid implantation without need for blood conduit  
Ability to restore cardiac function

### Market

The potential market (USA) for mechanical heart assistance devices has been estimated at over 1 million per year by 2011.

### Information Available

An information memorandum is available for this Invention which is currently held within a company called Heart Assist Technologies Pty Ltd.

**Industry:** Medical Device/Technology

**Proposed Business:** A unique implantable, non-blood contacting, direct cardiac compression device to assist the failing heart.

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## ***Business Description***

After eight years of intense research and development completed by the team in the Cardiac Technology Centre at Royal North Shore Hospital in Sydney, Heart Assist Technologies Pty Ltd was formed to develop their unique implantable direct cardiac compression (DCC) 'Heart Patch' to the stage of clinical trialling. The Heart Patch is an implantable cardiac assist device to boost the pumping capacity of failing hearts. The device is small, easily implantable, and non-blood contacting thus avoiding the risk of blood clots. It has been shown to be effective in assisting a severely failing, and even an arrested heart, by restoring and boosting the pumping capacity to near normal levels. In doing this, it restores the quality of life of the people with heart failure.

## ***Value Proposition***

The technology has had rigorous proof of principle involving extensive animal testing (in sheep), and presentations at scientific meetings both nationally and internationally attracting prestigious prizes and awards.

## ***Potential Market Applications of the Technology***

Heart failure is increasing with 5 million sufferers in the USA alone. Many of them are survivors of a heart attack. The management of heart failure patients consumes health resources and strains sufferers, families and institutions.

## ***Competitors***

Flow-through devices (not in the same category as the Heart Patch) which are currently available or under development are manufactured by Novacor, WorldHeart, Thoratec, Abiomed, and Arrow Intl. To our knowledge no other manufacturer has entered clinical trials for a DCC device in a similar category to the Heart Patch.

## ***Sustainable Advantage***

The team in the Cardiac Technology Centre at Royal North Shore Hospital in Sydney, has developed a unique implantable direct cardiac compression 'Heart Patch' to the stage of clinical trialling. The principle of operation of the device has been extensively tested in animal model of heart failure. The non-blood contacting characteristic of the Heart Patch provides significant regulatory affairs advantages for the potential registration of the device, and a shorter time to market when compared to other implantable devices.

## Status of Intellectual Property

Several patents have been filed to protect the technology and are fully owned by Heart Assist Technologies Pty Ltd.

- WO2005014082-An Implantable direct cardiac compression device and system.
- US2004106871, EP1363536-Determining the volume of a normal heart and its pathological and treated variants by using dimension sensors.
- AU5199300/AU742406, BR0011694, CA2377362, and CN1364091/CN1167472, EP1191958, HU0201733-An assist device for the failing heart.
- NZ515492-A heart actuator device for use in treating the failing heart.
- Other national phase applications have been entered.

# NS

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## **5. Immunoprecipitation Tube – Making Immunoprecipitation Easier**

### ***Business Opportunity***

The Immunoprecipitation Tube is a practical solution for performing the laboratory technique of immunoprecipitation. This is done with a single tube, halving the time taken, reducing experimental error, and improving consistency of results. This tube lends itself to being part of a 'kit', the 'kit' being tube + beads + antibody.

### ***Value Proposition***

The Immunoprecipitation Tube is a very practical solution that uses a single tube making it faster, easier and more accurate.

The laboratory technique of immunoprecipitation is an extremely common procedure carried out in cell biology research. It involves immobilising the protein of interest on a form of bead and later removing it. Sounds simple? However it currently takes 23 steps to do and involves mixing, centrifuging (repeatedly), aspirating (repeatedly), washing (repeatedly), heating, transferring and loading onto a gel. This common laboratory procedure has a high degree of experimental error associated with it, demands manual skill, and is time-consuming and tedious.

### ***Potential Market Applications of the Technology***

The common technique of immunoprecipitation is used by all basic biomedical scientists throughout the world. It is used in biochemical laboratories, hospitals, universities, drug development companies, pharmaceutical research departments, veterinary laboratories, medical research institutes and so on.

It is also used in proteomics, genomics and most biological research. Any laboratory scientist wanting a more accurate way to do immunoprecipitation will be interested in this product. The tube also lends itself to being part of a kit; the 'kit' being the tube + beads + antibody.

### ***Competitors***

Other immunoprecipitation tubes have been developed but they do not solve the problem as effectively as this tube. The majority of scientists are still using the conventional method for immunoprecipitation which has considerable experimental error associated with it.

### ***Sustainable Advantage***

This new immunoprecipitation tube helps a scientist to perform immunoprecipitation more accurately, more quickly and more easily than conventional methods. The tube prototype and method have been both tested and validated.

### ***Status of Intellectual Property***

A Provisional Patent Application was filed in June 2005.

### ***Proposed Business***

Immunoprecipitation tube/kit used to perform the common technique of immunoprecipitation or affinity purification.

### ***Contact***

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## 6. Augmented Baby Simulator for use in Emergency Life Support Training

### Business Opportunity

In emergency life support situations for babies, there are only a few elements that really count. This invention uniquely captures those elements.

Great improvements have been made in training emergency personnel in life support skills by using artificial patients (simulators). For \$2,000-\$15,000 a realistic looking but “dead” baby manikin is available - a plastic body on which a trainee can practice various skills. For \$250,000-\$500,000 complex physiological responses can be simulated in child and adult manikins: eyes open, arms move, patients breathe and respond to stimuli.

This baby simulator augments the standard lifeless baby manikin by bringing it to life with the widely used A-B-C resuscitation algorithm – airways, breathing and circulation. It also provides accompanying educational material so professional training sessions are immediately ready and available for trainers.

The opportunity to licence the augmented elements that make up this baby simulator and add them to an existing baby manikin, together with professional training material, is now on offer. The same simple, portable augmentation system can also be used on child and adult manikins.

### Market

Training in basic life support is expanding. Not only is it required by paramedics, doctors, nurses and other health care professionals but also by fire officers, police officers, emergency service personnel, defence forces and a wide range of community groups such as surf life savers. All of these markets are at an immature stage regarding use of simulated training products.

For infant life support, depending on the price point, there is a minimum current market potential of 10,000 units. Once the more life-like augmented baby manikin is experienced, trainers and trainees alike demand the added realism of a simulated baby. It will eventually replace the static baby manikin now on offer.

The same augmentation system can be used on child and adult manikins permitting cheaper simulators in these age groups

## *Technology*

The simulator is based on the widely used Laerdal ALS baby manikin. The augmented features are controlled by a simple set of analogue controls. They are chest movement, breath sounds, pneumothorax (unilateral air entry), umbilical pulse, right brachial pulse, blood pressure measurement by palpation and pulse oximetry. These features make possible a wide range of training scenarios.

The training package addresses a half-day small group workshop on Resuscitation of the Newborn and is very suitable for teaching infant resuscitation techniques. It includes a course outline, slide set with speakers' notes, skills work-sheets and evaluation form, scenario outlines and course evaluation form.

## *Status of Intellectual Property*

A United States patent has been granted. The patent application is under examination in Canada.

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## **7. Temperature-indicator Dispersive Electrodes for a New Standard of safety in Electrosurgery**

### ***The Technology***

Our clinical research team has designed a new technology enabling the temperature of dispersive electrodes to be determined at a glance. The ingeniously simple technique produces unique graded temperature indications, ideal for theatre assistants to monitor temperature build-up from current return, and to prevent burns at the dispersive electrode site. The technology can be adapted to standard dispersive electrodes with negligible increase in manufacturing cost, but significant improvements in safety.

It should be noted that this technology does not require the use of any additional monitoring equipment or sensors such as thermocouples or thermistors.

### ***Applications***

This system can be applied for electro surgery, particularly with high powered diathermy and Radio-Frequency (RF) ablation in Cardiology/Cardiac surgery, Obstetric and Gynaecological surgery and General surgery.

The technology could be used alone or combined with other burn prevention technologies on both capacitative and resistive dispersive electrodes, e.g. thermocouples or equipotential rings.

A simple, cost-effective advantage to prevent Dispersive Electrode Burns.

### ***Market***

The global and US electrosurgery markets are valued at greater than US\$550 million and US\$300 million respectively, and are characterized by intense, entrenched competition. Market leaders e.g. Tyco-Valleylab, expected 5-8% revenue growth in the market to 2006. Approximately 85% of all surgical procedures use electrosurgery and 70% of injuries reported during electrosurgery are from dispersive electrode burns.

### ***IP Position***

A Provisional Patent application was filed in 2004 and PCT in 2005 which is fully owned by Sydney West Area Health Service.

## Commercialisation

Sydney West Area Health Service is seeking a partner to licence our technology for the manufacture, distribution and sale of temperature-indicator dispersive electrodes. The licensee may fast-track regulatory approvals through clinical trials at Westmead Hospital with our clinical professionals.

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## 8. Oropharyngeal Airway Device

### Summary

A unique airway device with a novel nasal-intubation design, for combining single-use airway management and fiberoptic bronchoscopy.

The new Airway combines an inexpensive, effective single-use basic airway management device with a versatile difficult intubation aid, allowing rapid and safe transition from basic to advanced airway management.

### Market

Oral airway devices are found throughout hospitals in every 'crash-cart' and anaesthetist's kit, and in emergency vehicles and field kits. They are a universal, staple medical consumable. Multiple companies manufacture 'me too' copies of the Guedel, serving a huge market worldwide.

The novel airway can be marketed for high volume manufacture and sale as the 'smarter, more modern' alternative to the standard, near-universal basic airway support device, the Guedel. It may also be marketed specifically for difficult airway management cases as the only device designed to facilitate bronchoscopically-guided intubation through the nose or mouth in unconscious patients.

### Benefits

The basic universal airway design, the Guedel, has not changed in 70 years despite the advent of standard anaesthetic circuit connectors, the fiberoptic bronchoscope and other advances in airway management technology. This new airway is an effective single-use basic airway management device designed with a more anatomically correct curve for airway management. It can allow the patient to breathe spontaneously through the device under a conventional mask or while connected to an anaesthetic circuit. The patient can be ventilated using a traditional 'bag and mask' technique or connected to the anaesthetic circuit. It is cost effective for high volume production. It is a simple design, easy to manufacture in polyurethane from an uncomplicated mould similar to a Guedel, but with technical and design superiority to command a higher retail price.

## Nasal-intubation through an Oropharyngeal Airway

### *The Prin Airway:*

An unparalleled advantage in combining single-use airway management and fibreoptic bronchoscopy.

### *The Technology*

The Prin Airway is an easy-to manufacture and easy-to-use disposable airway device designed to provide support in both basic and advanced airway management problems.

As a basic airway the Prin Airway surpasses the Guedel, with a fit and functionality that caters for the advances made in airway management since the original Guedel's release.

The unique architecture of the Airway's pharyngeal arc and laryngopharyngeal ring better fits the orolaryngopharynx. The internal diameter of the device permits the comfortable passage of a standard 7.0mm endotracheal tube. A novel second orifice naturally aligns a conduit between the oropharynx and nasopharynx for facile endoscopic nasotracheal intubation. The novel laryngopharyngeal ring permits removal of the airway without disengaging the naso-endoscope. The Prin Airway can be used with a traditional face mask or connected directly to a standard anaesthesia circuit, allowing fibreoptic intubation more safely in unconscious patients, whether spontaneously breathing or not.

### *Applications and Advantages*

The Prin Airway is the obvious replacement for Guedel-style airways for:

- In-hospital airway management.
- Pre-hospital emergency and trauma airway management.
- Assisting endoscopic oro- or nasotracheal intubation in unconscious patients.

### *Market*

Failures are reported in up to 9.5% of orotracheal fibreoptic intubations through airways<sub>1</sub>, and current airway devices have major deficiencies in endoscopic functionality<sub>2</sub> – the Prin airway can alleviate these problems. From US\$517 million in 1999, the US Emergency and Trauma devices market had a predicted growth of 19.8% (CAGR) including the airways and breathing products market. New airway devices have captured large markets, e.g. LMA's are used in more than 100 million patients globally, and the PAXpress™ has a predicted market of US\$80million.

## **IP Position**

An international PCT application was filed on 23 March 2005.

## **Commercialisation**

We seek a license or purchase of our technology for manufacture, distribution and sale of the Prin Airway. The assignee may partner with our clinical professionals for further pre-clinical development or to fast-track regulatory approvals through clinical trials.

### Footnotes

1 – Eur J Anaesthesiol. 1997 Jul; 14(4):380-4. Comparison between the Ovassapian intubating airway and the Berman intubating airway in fiberoptic intubation. Randell T, Valli H, Hakala P.

2 – Curr Opin Anesthesiol. 2004 Dec; 17(6):505-510. The Williams Airway Intubator, the Ovassapian Airway and the Berman Airway as upper airway conduits for fiberoptic bronchoscopy in patients with difficult airways. Greenland KB, Irwin MG.

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## 9. Combining Forces to Improve Artificial Muscles

### Business Opportunity

A licence opportunity exists for a company interested in commercialising a new method of actuation (movement) using intelligent materials or artificial muscles. The simple yet effective method overcomes a major hurdle in the industry - how to scale up small efficient intelligent materials into large scale actuators without the loss of overall efficiency.

Most types of artificial muscle (such as intelligent polymers or shape memory alloys) show promising results when examined in small volumes/lengths. This is because, in most cases, efficiency grows with decrease in size of the material. The practical problem in producing viable actuators from these types of materials has been how to scale them up without the loss of efficiency.

Northern Sydney Central Coast Health researchers have devised a method that emulates natural muscles by using a large number of micro actuators that work together to produce large-scale strokes and forces.

A potential platform technology, the result is a novel assembly that can combine, summate, and amplify the forces and movements generated by multiple units of intelligent material.

This technology is applicable to a wide range of scales from micro to macro. Once made into a feasible, practical solution, the technology can be used to aid several different types of actuators with diverse characteristics. Through miniaturisation (achievable due to its simple structures), the invention has the potential to become a platform technology with applications in Nanotechnology.

### Market

Intelligent Materials are the future in actuation. Their higher efficiency and energy densities exceed what is currently available through electric, hydraulic, pneumatic or chemical motors/actuators.

Improving the usefulness of Intelligent Materials will benefit biomedical applications (particularly in biomechanical rehabilitation and artificial muscles), as well as applications in robotics, and the automotive and aerospace industry.

The sensor/actuator market is estimated to grow at a cumulative average annual rate of 21% between now and 2010 (IC Insights). By 2010, sensor/actuator sales will reach nearly US\$12 billion.

About 80% of sensors/actuators employ microelectro-mechanical systems (MEMS) technology to perform transducer functions. The latest YOLE forecasts indicate that the micro MEMS markets will grow from US\$5.1B to US\$9.7B, representing an annual growth rate close to 15%.

## **Investment Opportunity**

Northern Sydney Central Coast Health is seeking a partner able to prototype and commercially develop this technology in the exciting area of Intelligent Material actuation.

The present invention offers a method for solving a major hurdle in the industry, namely how to scale up small efficient Intelligent Material into large-scale useful actuators.

The nature of the investment would be through a licence deal.

## **Status of Intellectual Property**

Australian Provisional application #2006900944 Mechanical Actuation System filed on 24 February 2006.

## **Technology Investment Brief**

Industry	Sensors/Actuators
Proposed Business	Actuators for intelligent material applications

## **Team**

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## 10. The IV Hanger

### Summary

The convenience and safety of semi-automatic IV-pole and bed coupling and transfer has been an unmet need for both hospital and OH&S staff. However a Northern Sydney Central Coast Health invention called the 'IV Hanger' remedies this need. The IV Hanger provides automatic attachment and release of IV poles to hospital beds in-transit. This device is set to open up this previously unmet market, because competitors have not provided cost or functional benefits enough to justify mass uptake.

### Applications and Advantages

The IV Hanger is the obvious standard for in-hospital IV-pole and bed transport coupling. The unique design provides 'automatic' attachment and release of IV poles from hospital beds as the bed is raised or lowered; minimizing handling before, during and after patient transit, and reducing the number of staff required during transfer. It is a portable device that increases the efficiency and economics of transferring IV medications and poles coupled to hospital beds, and is easy-to-manufacture and easy-to-use. There is a reduced risk to staff and patients through reduced transfer of medications and minimal manual handling.

Patient and IV transfer is made safer, easier and more economic. The versatile design can be a stand-alone, portable device, or incorporated into bed and IV pole design to create new value-added versions of both products.

### Market

There is a potential global market for multiple units in any hospital worldwide. Competitor devices' disadvantages preclude their mass-uptake and include the "IV-Ease" (Ergotech Healthsystems; Sydney, AUS) which is mechanically complicated, over-expensive and not automated; the Clamp-and-Go<sup>®</sup> (Conrad Boettger, KS, USA) which has limited, non-automatic coupling positions and a mechanically complicated and expensive articulated arm; and the overly-complex Messerli Connection<sup>®</sup> (MEI Corporation, NE, USA).

Time-motion studies indicate IV-pole to bed coupling devices can save thousands of dollars per unit and provide saving through return on investment of up to 350% in the first year of use.

## **Commercialisation**

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The very first order for the IV Hanger has already been placed for pilot-use in Royal North Shore Hospital theatres in Sydney Australia. The device is currently under manufacture by a contractor and the NSCCH Office of Commercialisation is actively contacting multi-national companies seeking a partner to license or purchase the patented IV Hanger for local and international manufacture, distribution and sale.

## **IP Position**

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A provisional patent application for the IV Hanger is fully owned by Northern Sydney Central Coast Area Health Service, Sydney, Australia.

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## ***B. Drugs/Vaccines***

# 1. Serotype Identification Technology for Streptococcus Pneumoniae and Group B Streptococcus

## Summary

Infections caused by pneumococci are a major cause of morbidity and mortality especially among young children and the elderly worldwide. The development of novel diagnostic and therapeutic vaccines is enabled by the identification of all ninety streptococcus pneumoniae and all nine Group B streptococcus serotypes.

The technology was developed under the leadership of Professor Gwendolyn Gilbert, Director, Centre for Infectious Diseases and Microbiology Laboratory Services. It enjoys strong patent protection.

## Market

The global market for a Group B Streptococcus vaccine is estimated at over \$US700mill. The market for diagnostic and bacterial resistant probes is estimated at US\$3bill by 2006.

## Benefits

Rapid product development of both diagnostics and therapeutics could be undertaken using this serotyping technology to enable the development of superior products to meet the large projected demand for vaccines over the next few years.

## The Technology

We have developed a molecular capsular type prediction system for all 90 Streptococcus pneumoniae serotypes and all 9 GBS serotypes, based on a combination of partial sequencing of the respective cps gene clusters and serotype- or serogroup-specific PCR.

## Applications

The technology can be used for serotype identification in diagnostic kits, surveillance studies, as well as in vaccine development.

## Market

The diagnostic and bacterial resistance genetic probes market is estimated at US\$3 billion by 2006.

In 2002 The US Centers for Disease Control (CDC) introduced new guidelines for universal mandatory testing for GBS on all pregnant women at 37-39 weeks gestation. There is a global move to adopt CDC guidelines.

One commercially available Streptococcus pneumoniae vaccine, 7-valent Wyeth vaccine (Prevenar) - 2002 global sales >\$1 Billion.

In development - GlaxoSmithKline, Streptorix - (phase III trials); paediatric, 11 valent conjugate vaccine; Streptococcus pneumoniae elderly (phase I trials); adult, 23-valent polysaccharide vaccine.

Global GBS vaccine market is estimated at US\$700 million. No commercially available GBS vaccine. One company is at the stage of Phase II trials (Microscience).

## IP Position

Sydney West Area Health Service (SWAHS) has a PCT filed April 13th, 2004 for selected combinations of sequences for identification of all 90 serotypes of Streptococcus pneumoniae. National phase applications submitted for GBS serotyping sequences in Japan and USA (March 19th, 2004), Australia, South Africa, and Europe (April 19th, 2004), and China (May 19th, 2004).

## Commercialisation

SWAHS is seeking a partner for the manufacture, distribution, and sale of diagnostic kits, microarrays/biochips using our serotype identification technology. The licensee may also take advantage of faster, more robust and cost-effective methodologies recently developed by our scientists, which may be applied for other infections in addition to Streptococcus pneumoniae and GBS.

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Office of Commercialisation

## 2. Treatment for Multiple Sclerosis (MS)

### Summary

A genetic indicator for Primary Progressive Multiple Sclerosis (PPMS) has been identified. Methods to manipulate the genetic indicator as a polypeptide or nucleic acid or inhibitor, or combined with a carrier, potentially offer a novel method to treat MS. This technology offers the opportunity for the rapid development of a marker for MS and the potential development of novel therapeutic agents.

The technology has been developed by Professor Graeme Stewart, Director, Institute for Immunology & Allergy Research, Westmead Hospital, Sydney, Australia and key researcher Dr David Booth, and has been protected by patent. Animal trials are currently being completed in vivo in a highly regarded PPMS mouse model for the disease.

### Market

PPMS is diagnosed in approximately 10% of MS patients, with diagnosis usually occurring after the patient has been living for a period of time with progressive but not acute attacks. Of the estimated 3 million MS patients worldwide (350,000 in US, or 1 in 1000 over age 30) women are twice as susceptible as men. The incidence or prevalence of PPMS is between 450,000 to 960,000 people worldwide.

In 2003 56% of MS drug global sales were in the US (US\$1.9 billion) and the remainder largely in Europe (43%, US\$1.4 billion). Analysts expect market growth from US\$3.5 billion currently to US\$6 billion over the next few years. Global sales of leading drugs include:

Avonex (Biogen/Idec)	-	US\$1.16 billion
Betaseron/Betaferon (Berlex Labs/Schering AG)	-	US\$ 870 million
Rebif (Serono)	-	US\$ 819 million
Copaxone (Teva)	-	US\$ 720 million

### Benefits

The technology would allow PPMS sufferers to be diagnosed immediately and then potentially treated for the protein down regulated in the disease, to modulate disease activity rather than just treat symptoms.

Currently no treatment for MS is uniformly effective and most only treat symptoms. Corticosteroids used to shorten the duration of relapses can only be used for short periods due to severe side-effects. The typical cocktail of drugs to treat symptoms such as muscle spasms, urinary incontinence, pain, tremors, fatigue and depression are relatively ineffective.

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Office of Commercialisation

## 3. A Treatment to Prevent Type 1 Diabetes

### Summary

Type I diabetes is mediated by the destruction of beta cells. Proteins which control the two major processes implicated in the pathogenesis of Type I diabetes have been identified and characterized. This protein has been shown to be naturally occurring in the body and to be well tolerated in higher doses.

### Market

Type I diabetes occurs widely, especially in children, and currently affects about 4.9 million people worldwide. Its incidence in children under 5 has grown by 30% in the last 5 years. This technology would target the at-risk portion of the population with the potential to prevent or delay the onset of the condition.

### Benefits

The treatment of Type I diabetes meets an unmet need, as to date there are no effective treatments against this disease which is increasing in prevalence.

### The Opportunity

For the first time, we have found strong evidence that a known protein prevents or delays the onset of Type 1 diabetes in an effective animal model for the disease.

Drs Chris Jackson and Meilang Xue's research at Royal North Shore Hospital and the University of Sydney, has found the ideal candidate to prevent Type 1 diabetes. The protein has the potential to prevent the immune and inflammatory destruction of beta cells, the two major processes implicated in the development of the disease, and it has a proven track record as a safe therapeutic agent.

Northern Sydney Central Coast Area Health Service is seeking to license the technology to a drug development company interested in taking the project to clinical trial stage.

## Background

Type 1 diabetes is believed to be caused by interplay between genetic susceptibility and environmental factors. The disease is lifelong and incurable, striking people in their childhood years and making them insulin dependent for life.

### **What are the current and future market opportunities?**

Type 1 diabetes accounts for up to 15% of all diabetes and currently affects 4.9 million people around the world. Young relatives of the 4.9 million people with Type 1 diabetes are more likely to get the disease, and if they have antibodies that indicate an autoimmune attack against the insulin-producing cells in their own pancreas, their risk is very high.

This is the 'highly at risk' target market for applying the protein to prevent the onset of type 1 diabetes. By taking advantage of the relatively long pre-diabetic period, their diabetes related autoantibodies can be measured and if found to be in a pre diabetic state, treatment with the protein can be given to prevent onset of the disease.

The Type 1 diabetes market is growing with a 30% increase in children under 5 years developing the disease in the last five years.

### **What is the competition?**

There is still nothing on the market to prevent Type 1 diabetes. Competing approaches have had mixed success. Trials of antigen based treatment with insulin in the 1990's and the nicotinamide trial reported in 2002, did not, overall, slow the progression of diabetes.

Recently, other potential therapeutic agents such as an antibody to the CD3 receptor, an antibody to prevent RAE-1 from binding its receptor on the CD8 lymphocytes, dendritic cells to stimulate T-cells, and a nasal insulin spray are showing more promising results to prevent diabetes.

Other agents have been reported to prevent or delay the onset of diabetes in animal models. These include active Vitamin D, a green tea derivative -epigallocatechin gallate, streptozotocin-treated islet cells, and a diet containing low advanced glycolation end products. The effect of these agents is yet to be tested in human diabetes.

### **What qualities of the product make it unique or provide a competitive edge over other potential technologies in the market place?**

In contrast to the current approaches which focus on the immune response in diabetes, this protein is unique in that it not only targets the abnormal immune response but also directly inhibits inflammation, which is associated with insulinitis. Thus, the protein controls the two major processes implicated in the pathogenesis of Type1 diabetes, inflammation and auto-

immunity. This explains how it dramatically reduced blood glucose levels and prevented diabetes in non-obese diabetic mice.

Unlike many of the other proposed agents to prevent diabetes, this protein has a proven track record as a safe therapeutic agent, a very important consideration when treating children.

The protein is a naturally occurring protein circulating in the blood and it can be produced in large quantities using recombinant techniques. It is well-tolerated when used to treat patients with a severe illness at relatively high doses. Its safety data indicates that it may also be suitable for use in high-risk pregnancies which develop gestational diabetes.

### **Has the technology been proven?**

The protein has been proven in vitro and in vivo in a highly regarded animal model for the disease, the non-obese diabetic mouse model. It has been shown to prevent the immune and inflammatory destruction of beta cells and has a proven track record as a safe therapeutic agent.

It has yet to be trialed in humans to prevent Type 1 diabetes.

### **Patent Pending**

An International (PCT) Patent Application No PCT/AU2006/000009 was filed on 9 January 2006 with priority from Australian Provisional Patent Application No 2005 900073 "Treatment for Autoimmune and Inflammatory Conditions " filed by Northern Sydney Central Coast Area Health Service on 7 January, 2005.

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## 4. Improving Pregnancy Rates Using Assisted Reproduction Technologies

### Summary

A novel drug treatment to improve the pregnancy rate for in vitro fertilization and artificial insemination by improving the viability of embryos.

### Market

The IVF market continues to grow rapidly as it is estimated there are over 80mill people worldwide with fertility issues. This technology is unique.

It also has application in livestock production.

### Benefits

IVF is an expensive technology which has a low rate of success (10-20%). An increase in the success rate would enable wider access and reduce the cost to the healthcare system from failed IVF treatment.

### The Opportunity

After several years of intensive research, Associate Professor Chris O'Neill from the University of Sydney and Royal North Shore Hospital has discovered how to dramatically improve the viability of embryos produced using assisted reproductive technologies (ART), by treating them with a small molecule drug. This is a breakthrough to improve pregnancy rates (currently a low 10-20%) during infertility treatment.

It also applies to livestock production where rapid genetic improvements are facilitated by ART, yet 40% of cattle embryos continue to die in vivo – a significant deterrent to its economic use.

### Value Proposition

This invention addresses the problem of poor pregnancy rates when using assisted reproduction therapies such as human IVF or artificial insemination (AI)/embryo transfer in animal breeding. Its ability to make healthier babies resulting in more successful pregnancies, will improve the cost-benefit of artificial reproduction technologies. This will significantly increase the worldwide market.

## ***Potential Market Applications for the Technology***

Infertility is a problem for 80 million people worldwide or about one in ten couples. This invention has the potential to be used in all ART treatments which numbered about 7.8 million in 2000. Markets are relatively immature and doubling every two years. The target market is the specialised infertility clinic/laboratory and obstetricians specialising in infertility.

A further market is in embryonic stem cells.

With regard to livestock production, if this technology improves the success of artificial insemination by only 10-15%, it will create a major market expansion. The target market is the large AI/ART companies in Agriculture. Proof-of-concept in bovines would be the initial market entry point.

Cook Australia P/L is a very interested potential partner.

## ***Competitors***

This is a breakthrough discovery for assisted reproduction technologies and there are, as yet, no competitors. Attempts at treatment of various stressors on the embryo have had only limited success and have not been able to reduce embryo death. Safety of the proposed treatment is the primary concern and this can be determined in planned animal studies over the next 2 years.

## ***Sustainable Advantage***

Medical treatment of the embryo is a new therapeutic strategy. As such it will have to sustain exhaustive tests to ensure there is no biological risk for the embryo. If successful, the drug will effectively treat a defect in embryos that is induced by the assisted reproduction process and results in the disappointingly low pregnancy rates (10%-20%). It will be alone in its ability to do this for the immediate future.

Further development of the IP is feasible and could lead to additional blocking patents.

## ***Status of Intellectual Property***

International (PCT) Patent Application No. PCT/AU2004/001121 'Methods for Enhancing Embryo Viability' Christopher O'Neill (inventor) was filed on 20 August, 2004. The IP is owned exclusively by Northern Sydney Area Health Service (now called Northern Sydney and Central Coast Area Health Service). The patent application is undergoing an International Preliminary Examination. It has entered the National phase in Europe, the US, Canada, China and Australia.

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## **5. Novel Drug Combination to Reduce Blood Pressure in Older People**

### **Summary**

There are a growing number of people over 65 years with raised systolic blood pressure that is notoriously unresponsive to conventional treatment. This treatment reduces their systolic blood pressure by a unique combination of drugs which individually are well known to have no appreciable toxicity. The combination has been successfully trialled in a small sample of the target population.

### **Market**

In the USA alone, this treatment would reduce the risk of heart attack and stroke for 16 million people in the over 65 age group with systolic hypertension.

### **Benefit**

This treatment meets an unmet need for a significant patient population in the over 65 age group.

### **The Opportunity:**

This is a combination drug which combines at least one angiotensin II inhibitor with at least one nitric oxide donor. The synergistic antihypertensive combination is for the treatment of systolic hypertension in older people (over 65 years) and/or patients with isolated systolic hypertension (ISH). The new treatment, aimed specifically at the +60 age group, requires a large, appropriately selected clinical trial to provide proof of concept. The inventor, Gordon Stokes, is an international expert in hypertension.

### **Value Proposition**

There are a growing number of people over 65 years with raised systolic blood pressure that is notoriously unresponsive to conventional treatment. This puts them at much greater risk of heart attack and stroke. This treatment reduces their systolic blood pressure by a unique combination of drugs which individually are well known to have no appreciable toxicity. Its synergistic combination provides greater efficacy than any known conventional therapy for this condition in older people.

## ***Potential Market Applications of the Technology***

22 million people over 65 in the US suffer from systolic hypertension and there are approximately 1 million in Canada. Because the failure rate of conventional treatment is as high as 75% as people become older, the real target market are those 16 million who fail conventional treatment consisting of the current antihypertensives.

## ***Competitors***

Older people have the poorest rates of achieving blood pressure control and there is nothing on the market as effective as this new drug at treating those with isolated systolic hypertension and endothelial dysfunction. Nitrates have not been used in the chronic treatment of hypertension before and it needs to be demonstrated that nitrate tolerance can be overcome. BiDil, a nitric oxide combination drug developed by Nitromed Inc was successfully used to treat Afro-Americans for heart failure in the A-HeFT trial, showing a 43% improvement in survival. This result provides evidence that nitric oxide based drugs have real potential.

## ***Sustainable Advantage***

The failure rate of conventional treatment for systolic hypertension as people become older can be as high as 75%. This invention provides an effective treatment that has been shown to work in controlled trials in a small number of older people with chronic systolic hypertension, for as long as 5 years to date. The therapy is specific and selective in regard to correcting the basic defect causing systolic hypertension, and supplying the appropriate blend of systolic versus diastolic blood pressure decrease.

## ***Status of Intellectual Property***

Patent Applications have been made in the US 19/ 255, 447 and Canada, and the US application is undergoing Examination. The patents are owned by Northern Sydney Area Health Service (now called Northern Sydney and Central Coast Area Health Service) and are entitled 'Composition and Method of Treating Hypertension', inventor Gordon Stokes. A combination series of drugs combining at least one angiotensin II inhibitor and at least one nitric oxide donor for the treatment of systolic hypertension in older people (+60 years) and/or patients with isolated systolic hypertension.

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## 6. The Fourth Class of Drugs to Treat Heart Failure

### Summary

A new class of drugs to treat heart failure has been identified. The drugs are aimed at restoring heart function after heart failure. Drugs have already been trialled (unsuccessfully) for other diseases and were shown to have no negative cardiovascular effects.

### Market

Heart failure affects about 2% of the population with a five year mortality rate of 50%. The estimated number of patients is approximately 14mill in the western world which gives a market size of US\$15bill.

### Benefits

This new class of drugs provides for a new strategy to treat heart failure which will complement and enhance existing treatments.

### The Opportunity

While flying over Fiji, Professor Helge H Rasmussen and Dr Henning Bundgaard from Royal North Shore Hospital and the University of Sydney developed a major paradigm shift for clinical treatment of patients with heart failure. Extensive in vitro studies followed, supporting the new paradigm, and a pivotal study in sheep later confirmed it. They had discovered a new class of drugs that could be used in the treatment of heart failure.

The drugs studied by Rasmussen and Bundgaard belong to a group of orally active drugs of different chemical composition but with one particular biological property in common. Drugs that possess this property have been developed by several pharmaceutical companies for other purposes for which they have not been effective. Those that have reached phase II clinical trials in humans have reported no cardiovascular side effects. This new class of drugs will improve the pumping action of the failing heart and ameliorate the profound social impact that heart failure has on patients and families.

### Value Proposition

Heart failure (HF) occurs with a prevalence of about 2% in industrialised countries. It is characterised by a reduced pumping capacity of the heart and hence reduced perfusion of the body. Despite advances in treatment the 5-year mortality remains distressingly high at ~50%, and in some subgroups even higher. This is a new class of drugs that will be used to treat heart failure, enabling the heart to pump more strongly, restoring energy and improving survival.

## **Potential Market Applications of the Technology**

With ~14,000,000 patients with treatment-requiring HF in the USA, Western Europe and Japan there is a potential market size of ~ US\$15 billion annually if the cost of the single best known drug in Australia, carvedilol, is used as a bench mark. The incidence of Heart Failure is characterised as “epidemic” in the US. Heart Failure drug sales will be driven by the introduction of new, more effective drug compounds such as this new class and the ageing population.

## **Competitors**

This will be a fourth class of drugs used in the treatment of heart failure in addition to those currently used (angiotensin converting inhibitors, aldosterone antagonists and beta blockers) and could be more effective.

## **Sustainable Advantage**

More effective drugs are required to treat heart failure and this fourth class may prove to be it. Whereas the effects of the three presently used classes of drugs for heart failure (angiotensin converting inhibitors, aldosterone antagonists and beta-blockers) are limited to counterbalancing the effects of the heart failure-induced changes in the renin-angiotensin-aldosterone axis and in catecholamine levels, such a limitation will not apply to drugs from the fourth class. This may give this class of drugs superiority relative to the three existing classes of drugs.

## **Status of Intellectual Property**

An International (PCT) Patent Application no. PCT/AU2005/000590 was filed by Northern Sydney and Central Coast Area Health Service on 26 April 2005. The patent covers use in the treatment of HF of the class of drugs studied. The patent is undergoing International Examination.

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## **7. A Pre-Clinical Evaluation Service: Evaluate compounds in human cells before use in patients**

### *The Service*

A contract research and development service, using a patented human embryonic stem-cell (hESC) line and its clonal lines as a ground-breaking tool for in vitro toxicology/teratology, efficacy and safety studies which mimic the human model<sup>1</sup>. hESC-derived cell lineages with identifying tags will initially be developed in alliance with a Pharma/Biotech partner and will be used in high throughput screening of various compounds. Protocols will be developed to test new and existing compounds *in vitro* and will aim to meet regulatory approval (TGA/FDA/CE). The service will endeavor to meet the time- and cost-efficiency needs of small to large sized companies.

### *The Technology*

Our patented clinical embryonic stem cell line, designated Endeavour-1 (E1), is largely serum-free and xeno-free which may be cultured under feeder-free conditions. Currently four patented clonal cell lines (E1C1, E1C2, E1C3 and E1C4) have been derived from Endeavour-1, and each offers an opportunity for homogeneous populations of cells for toxicological/teratological screening of pharmaceutical compounds. Each of these cell lines has proven pluripotency and long-term self-renewal and the ability to be differentiated into cells that exhibit the characteristics of one or more of three germ layers such as ectoderm, mesoderm and endoderm.

### *Applications and Advantages*

- A convenient means for identifying the impact of compounds on humans without the ethical considerations associated with traditional studies in human subjects.
- A powerful pre-clinical research tool for new compounds under development.
- A complimentary dataset aimed to support clinical trial data for regulatory approval.
- A critical predictive tool for detecting side-effects (teratology) and adverse drug reactions (toxicity) of new and existing compounds that cannot be tested within the parameters of a clinical trial.
- A financial advantage to reduce risk associated with side-effects and adverse drug reactions identified post-marketing of a compound.

## Market

In the last four decades 2.9% of marketed drugs were withdrawn from the market due to severe adverse drug effects<sup>2</sup>. Withdrawal of a drug from the market does not only compromise a company's public image and harm the patient population it also causes a loss of potential revenues. The cost to develop a successful drug is estimated at \$800 million with an average development time of 12-15 years<sup>3</sup>. It is estimated that a drug manufacturer can reduce the cost of drug development by approximately \$350 million via an increased clinical success rate from 1 in 5 to 1 in 3 (saving \$221 million), and by reducing the total development and regulatory review time by 25% (saving \$219 million)<sup>4</sup>.

This service may be utilised by Pharmaceutical Manufacturers, Contract Research Organisations and smaller disease-focused companies to undertake pre-clinical toxicological/teratological studies that may indicate the potential success of clinical trial and/or as a complimentary dataset useful for local regulatory approval (FDA, CE or TGA). It is anticipated that all new compounds under development could be tested using this service to determine its likelihood of success in clinical trials. In addition, this service could be used to test drugs currently available in the market in order to identify potential adverse drug effects before the onset of harm to a company's public image, its revenue income and the patient population.

## Commercialisation

Estimated upfront costs of approximately \$250,000US per annum for 2 years will initially be required to develop the labeled-lineage-specific cell lines from hESC and protocols required for this service. Once the specific cell lineages have been purified, the service will be performed on a fee-for-service contract with all IP and publication rights reserved by the client. The terms of the service will require an upfront fee of 25% of total cost, an additional installment of 25% halfway during testing and the remaining 50% on receipt of the service report.

<sup>1</sup> C.W. Pouton and J.M. Haynes, Embryonic stem cells as a source of models for drug discovery. *Nature Reviews* 6 (2007) 605-616.

<sup>2</sup> K.E. Lasser, et.al., Timing of new black box warnings and withdrawals for prescription medications. *J. Am. Med. Assoc.* 87 (2002) 2215-2220.

<sup>3</sup> J.A. Dimasi, et.al., The price of innovation: new estimates of drug development costs. *J. Health Econ.* (2003) 151-185.

<sup>4</sup> J.A. DiMasi, The value of improving the productivity of the drug development process: faster times and better decisions. *Pharma-coeconomics* 20 (Suppl. 3) (2002) 1-10.

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## 8. A Therapeutic Antibody to Treat Chronic and Inflammatory Autoimmune Diseases

### Summary

Chronic inflammatory and autoimmune diseases are caused by inappropriate amplification and overproduction of T-helper cell type-1 (Th1) and IL-17 cytokines by human immune cells. These events and the pathological progression of a wide range of autoimmune diseases and inflammatory conditions are controlled by a transcription factor which has been proven to play an important role in both animal and clinical studies. We have identified and demonstrated that an antibody, specific to a surface-membrane antigen, can down-regulate the expression of this transcription factor and other inflammatory cytokine production in human immune cells. We have demonstrated and confirmed that the antibody is highly effective in suppressing joint inflammation in collagen-induced arthritis – a well-established *in vivo* mouse model of the human auto-immune disorder of rheumatoid arthritis.

### Potential Markets

Due to the mechanism of actions of the antibody in the pathological process, our treatment targets a wide range of autoimmune diseases (including rheumatoid arthritis, multiple sclerosis, type-1 diabetes mellitus, lupus nephritis, inflammatory bowel disease and psoriasis) and other inflammatory conditions (allograft transplantation rejection, graft versus host diseases, recurrent spontaneous abortion, failure of IVF implantation).

The market for these diseases is enormous considering that these are some of the most common conditions worldwide and their incidences are increasing. Rheumatoid arthritis affects 13 million people in America alone. Around 3 million people suffer from multiple sclerosis and nearly 5 million people have type-1 diabetes worldwide. Allograft rejection and graft versus host diseases are common problems in transplantation, while recurrent spontaneous abortion occurs in 10-15% of all pregnancies. The current annual global cost for the drug treatment of these diseases is in excess of US\$10 billion.

### Benefits

Currently there is no universally effective treatment for these diseases and most treatments only target symptoms rather than the pathology of the disease. Drugs like corticosteroids, cyclosporine and methotrexate are effective immunosuppressive drugs but all have severe side-effects. Furthermore, they are not suitable for use during pregnancy in the treatment of gestational diabetes or recurrent miscarriage because of their potentially toxic effects on the fetus. The antibody used in our treatment provides high specificity for the target, and being a natural biological agent, it has less risk of side-effects, liver or renal toxicity. It is suitable for use in pregnancy because it does not cross the placental barrier or affect maternal hormonal status.

Of equal importance, a major difference from other general immunosuppressive drugs (which suppress the immune response in a broad and non-specific manner that increases the risk of opportunistic infections), is that our therapeutic antibody specifically targets the amplification of pro-inflammatory cytokine production responsible for the disease without compromising immune competence by shutting down the immune response completely.

### *Status of Intellectual Property*

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The invention has been protected by an International (PCT) Patent application which is owned by Northern Sydney and Central Coast Area Health Service (NSCCH) and the University of Sydney. We are seeking to license the technology to a commercial partner able to humanize the antibody and take it through to human clinical trials in one or more disease indications.

### *Contact*

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## **9. Herpes Simplex Virus Types 1 and 2**

### **Unique peptide epitopes for vaccine and prognostic applications**

#### *The Technology*

In humans and/or murine models, Herpes Simplex Virus (HSV)-specific CD4 and CD8 T cells play a central role in controlling primary and recurrent HSV infections; both in recovery from infection and in restricting HSV spread in the nervous system. CD4 T cells recognize mainly structural proteins and especially glycoproteins D and B. This technology relates to peptide epitopes of HSV, in particular peptide epitopes of HSV-2 glycoprotein D and represents a new advancement in the detection, prevention and treatment of HSV. These immunodominant, cross reactive epitopes are actively recognised by patients naturally infected with either HSV-1 or HSV-2.

#### *Applications*

These cross reactive and cross protective epitopes may be applied to:

- methods and compositions for detection of the presence of and level of T cell immunity to HSV
- compositions for the prophylactic or therapeutic immunisation against infections of HSV1 and/or 2.

#### *Market*

HSV-1 and HSV-2 are closely related. HSV-1 causes predominantly oral, but also genital herpes. HSV-2 is responsible for genital herpes but rarely also may cause the oral form. 60-80% of western populations are infected with HSV-1 and 12-25% with HSV-2. The prevalence is much higher in some developing countries. Of the worldwide adult population infected with HSV-1 an estimated 56 million people are in developed western countries and among healthy adult populations, HSV-2 sero-prevalence is higher in the USA than in Europe.

The potential worldwide market for the treatment of HSV is estimated to be over €1B. There is currently no cure for HSV or a treatment to eradicate the virus from the body or prevent re-activation of the virus. The market potential for sensitive methods of detection, prophylactic or therapeutic vaccines are enormous and would be advantageous to patients, clinicians and health services alike. Moreover, this opportunity represents a landmark opportunity for Pharma to seize worldwide market dominance in the detection, prevention and treatment of HSV.

### **Competitive Advantages of Peptide Epitopes**

- cross-reactive for HSV-1 and HSV-2
- vaccine candidates for HSV-1 and HSV-2
- broadly recognized by the immune system and useful for most patients
- useful for patients infected with HSV-1 only
- useful in tests for T-cell immunity against HSV-1 and HSV-2
- 

### **IP Position**

A Provisional Patent Application has been filed.

### **Commercialisation**

We seek to out-license this technology for further development and market distribution.

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## ***C. Diagnostics/Therapeutics***

# 1. Predict Response and Increase Effectiveness of Cancer Chemotherapy

## Summary

A simple protein-based method to determine resistance to chemotherapy and potentially sensitize patients to platinum or taxol-based chemotherapeutics or alternative cancer drugs has been developed. Using the technology the researchers have been able to regulate the sensitivity of cloned cells to platinum chemotherapy. This technology offers the opportunity to develop a simple diagnostic test to predict likely response to therapeutic drugs used to treat common forms of cancer. It also offers the opportunity to develop adjunct therapies to increase sensitivity of chemotherapy drugs.

Professor Paul Harnett, Network Director of Cancer Services, SWAHS and his team have spearheaded the research in this area based on a clearly identified clinical need.

## Benefits

This technology offers the opportunity to create a unique position in this market - a provider of treatment methodologies and a personalized medicine approach to patients suffering from common cancers including:

- Predict response and increase effectiveness of cancer chemotherapy
- Protein-based tools to determine tumour-response to chemotherapy: A new advantage in treatment of cancer

## The Technology

Our clinical research team has developed a technology to measure and manipulate the sensitivity of human cancer to chemotherapy drugs.

The technology exploits proteins; both in their association with sensitivity to chemotherapy agents, and in their capacity to be used as tools to manage chemotherapy drug resistance - either directly, or in a pharmaceutical combination or genetic construct.

## Applications

The technology may be embodied in novel products, including:

- Patient-screening diagnostics - to select the most effective chemotherapy drug for a given patient (particularly platinum-, and potentially anthacycline- and taxane-based drugs).
- Novel pharmaceuticals with a variety of mechanisms - to increase cancer sensitivity to chemotherapy.
- Pre-clinical research tools - to assess and refine efficacy of NME's for chemotherapy.

The protein association with chemotherapy resistance has been proven in specific cancer patients as well as specific tumour cells, and potentially has applications across a range of cancers.

## Market

Chemotherapeutics are the most used drugs to treat cancer worldwide and the estimated market size is greater than \$US5bill. Market share in established chemotherapeutics is diminishing, due to generic competition after extensive patent expiries, and due to novel agents that exploit chemotherapy resistance. Forty percent of operable and 80% of inoperable cancers can be chemo-resistant, creating opportunities for new sensitizing agents and adjuncts that improve efficacy of current chemotherapy. The FDA is fast-tracking adjuncts to chemotherapy, including the chemo-sensitiser 'Phenoxodiol' (Marshall Edwards/Novogen).

## IP Position

A PCT application was filed in December 2005 and is fully owned by Sydney West Area Health Service.

## Commercialisation

We seek a partner to licence our technology for further development and to manufacture, distribute and sell diagnostics and novel pharmaceuticals using the technology. The licensee may partner with our clinical professionals for further research, pre-clinical development of NME's and to fast-track regulatory approvals through clinical trials.

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## 2. Cyclic peptides and uses thereof

### Summary

SWAHS scientists have developed synthetic cyclic peptides useful in the treatment and/or conditions associated with T-cell activation or function, microbial infections and cancer.

### Benefits

Our synthetic cyclic peptides with alternating D- and L- amino acids have improved efficacy and specificity compared to linear peptides, whilst lending the same, or greater, biological efficacy. By creating a cyclic peptide, oral delivery and pH stability are improved and enzyme degradation reduced, increasing the utility of the compound.

#### **The cyclic peptides have been tested in vitro:**

“Certain observations, when considered together with the cell viability and cell proliferation results, indicate that C1 is a very sensitive and potent inhibitor of T-cell activation under the normal antigen presenting system requiring the “macrophage” presenting the antigen to the T-cell of interest. Of all the activation systems tested, the antigen presentation mechanism is the closest representation of what actually occurs in an in-vivo environment. In this light, the fact that C1 inhibits IL-2 production demonstrates its potential for use as a treatment option for T-cell mediated conditions”.

In-vivo: The immunomodulatory effects of C1 in vivo were examined by using an adjuvant-induced arthritis model in Wistar rats and results showed effectiveness in reducing inflammation in this model.

Further, the cyclic peptides have also been very effective in antibacterial activity assays in cultures of organisms.

### Technology Investment Brief

**Industry:** Human Therapeutics

**Proposed Business:** Development of human therapeutics using synthetic cyclic peptides

## Team

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Dept. of Rheumatology  
Westmead Hospital  
SWAHS

Dr Marina Ali  
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Dr Veronika Bender  
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## The Technology

SWAHS scientists have developed synthetic cyclic peptides useful in the treatment and/or conditions associated with T-cell activation or function, microbial infections and cancer. A vast number of diseases and conditions are associated with T-cell function or activation. Accordingly, there is an ever present need for medicinal agents with immunomodulatory activity capable of mediating the activation and/or function of T-cells.

## Applications

Peptides of the present invention find application in the treatment or prevention of a variety of diseases and conditions. These include diseases in which inhibition of T-cell function is desirable, particularly auto-immune diseases and cancers, and may include neural diseases such as multiple sclerosis and Guillain Barre Syndrome; endocrine diseases such as diabetes, Hashimoto's disease and pernicious anaemia; skeletal diseases such as rheumatoid arthritis, ankylosing spondylitis, reactive arthritis and systemic lupus erythematosus; immune diseases such as transplant rejection syndrome, urticaria and drug allergy; dermal diseases such as pemphigus, eczema, contact dermatitis and psoriasis; gastrointestinal tract diseases such as ulcerative colitis and Crohn's disease; respiratory diseases such as asthma and pneumonitis; transplantation disease, cardiac diseases, vascular diseases and cancer.

## **Competitive advantage**

The present inventors have previously shown that a linear peptide, designated Core Peptide (CP), acts as an immunomodulatory agent and inhibits IL-2 production in T-cells following antigen recognition.

Our synthetic cyclic peptides with alternating D- and L- amino acids have improved efficacy and specificity compared to CP, whilst lending the same, or greater, biological efficacy as CP. By creating a cyclic peptide, oral delivery and pH stability are improved and enzyme degradation reduced, increasing the utility of the compound.

## **Market**

A 2004 Frost and Sullivan report states that the global therapeutic peptides market is currently valued at around \$1 billion (€756m), with Europe contributing about \$300m of that total, and will increase at around 10.5 per cent a year between 2003 and 2010. This means that the European market for peptides will double in size by 2010 to \$605m.

## **IP Position**

Sydney West Area Health Service (SWAHS) has lodged an Australian Provisional patent application # 2005906187, entitled "Cyclic Peptides and Uses Thereof".

## **Commercialisation**

SWAHS is seeking a partner to fund further research, further clinical validation and/or license our technology for the manufacture, distribution, and sale of any potential products incorporating our novel cyclic peptides.

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### **3. Outsmarting Brain Tumours: A protein test to improve diagnosis of brain tumours and predict responsiveness to treatment.**

#### *The Opportunity*

The discovery of new biomarkers that will dramatically improve brain tumour diagnosis has been made by a team of researchers from the Kolling Institute at Royal North Shore Hospital in Sydney, the CSIRO and the University of Sydney.

The gene-protein markers can differentiate brain tumours with aggressive properties and will help histopathologists to more accurately diagnose brain tumour types, predict the responsiveness of an individual to therapy, as well as predict likely survival.

We envisage this small panel of proteins with accurate diagnostic and prognostic features, being used as an additional test for brain tumours in routine neuropathology.

We are seeking companies interested in licensing the technology and developing a diagnostic test .

#### *Value Proposition*

This invention provides new robust markers to improve diagnosis of brain tumours, particularly in small biopsies where there is not much tissue and diagnostic error is high. To dramatically improve their diagnosis, it is envisaged the neuropathologist could simply add another two stains to the diagnostic process. A positive reaction to a given antibody will accurately predict the aggressiveness of a tumour, provide a more realistic prognosis for an individual and suggest a more personalised therapeutic treatment.

#### *Potential Market Applications of the Technology*

There is strong potential for the two gene-protein sets discovered from microarray analysis to be used as markers in a diagnostic kit. The results will narrow down diagnosis of brain tumours and make prognosis more accurate.

Whilst the two markers are present in brain and ovarian tumours, one marker is also present in colon, breast and gastrointestinal tumours, giving rise to further potential diagnostic applications. The genes are also a target for chemotherapy treatment.

### ***For brain tumours, these markers can be used widely:***

- To more precisely diagnose brain tumours by type or grade.
- To provide accurate grading of small biopsies to determine the tumour's aggressive potential.
- To provide accurate grading of brain tumours that are surgically inoperable, to determine their aggressive potential.
- To predict likely long term survival in brain tumour patients.
- To be the target of more effective cancer therapies for brain tumours.

### ***Limitations of Current Brain Tumour Diagnosis***

Aggressive, high grade brain tumours are currently classified by neuropathologists according to histopathological features: nuclear atypia, increased mitotic activity and the presence of necrosis and microvascular proliferation. Diagnostic error can be high particularly where there is not much tissue, and there are no robust markers available to predict patient outcome. This invention will help determine a tumour's aggressive potential and give clinicians more information to guide treatment.

### ***Sustainable Advantage.***

The markers can differentiate brain tumours with aggressive properties and will dramatically improve accuracy of brain tumour diagnosis.

### ***Status of Intellectual Property***

The Intellectual property is owned exclusively by Northern Sydney and Central Coast Health.

### ***Contact :***

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## 4. Simplified Photographic Method to Determine Your Risk of Obstructive Sleep Apnoea

### *The Investment Opportunity*

We have developed a simplified photographic method for determining whether a person is at risk of suffering from Obstructive Sleep Apnoea. It is easy to use and reliable. It could radically increase the numbers of people being diagnosed with Obstructive Sleep Apnoea. We are in the process of automating the patented method.

### *Background*

About 4% of males and 2% of females suffer from Obstructive Sleep Apnoea. It occurs when the airway temporarily collapses during sleep, preventing or restricting breathing for up to ten seconds or more. Such events occur several hundred times a night severely disrupting sleep.

Obstructive Sleep Apnoea is linked to a range of serious chronic diseases such as stroke, heart failure, hypertension, diabetes, obesity and coronary heart disease. It is also implicated in increased traffic and workplace accidents.

Despite the serious health consequences of untreated Obstructive Sleep Apnoea, about 90% of people who have it remain undiagnosed and untreated. One of the main reasons for this is because diagnosis is costly and time consuming. Resources such as Sleep Centres in hospitals cannot meet the demand so many patients go undetected and untreated.

### *The technology*

Researchers at Royal North Shore Hospital and the University of Sydney have found that by objectively quantifying a person's craniofacial anatomy through taking two digital photographs, they can predict the presence and severity of Obstructive Sleep Apnoea using mathematical and regression analysis.

For example, a physician may simply take both frontal and profile photographic images of the patient's head and neck (including the sternal notch) from which a variety of craniofacial landmarks may be identified. The photographs are either taken directly in a digital format using a digital camera, or if a digital camera is not available, the photographs would be converted into a digital format (i.e. scanned) such that the landmarks may be identified with reference to a pixel location (x, y) on the image. The selected measurements are then subsequently computed with respect to those landmarks. In essence, the measurements represent various dimensions of the craniofacial soft tissues compartments, bony compartments and a combination of both. The interaction between the relative sizes of these compartments is important in the pathogenesis of the condition.

### ***Automating the technology***

An automated prototype of the technology will be available within a few months and its reliability evaluated clinically in Sleep Centres in Sydney.

We are seeking licensees for the patented technology.

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## **5. Therapeutic Peptides**

### **A novel therapy for the inhibition of HIV infection**

#### ***The Technology***

The ability to engineer different protein-protein interactions based on charge has allowed researchers at the Sydney West Area Health Service (SWAHS) to test three different peptides for their effectiveness in inhibiting HIV-1 replication and infectivity. Infection assays have shown that lymphocytes treated with one such peptide (L) at the time of HIV infection or post-infection led to inhibition of HIV-1 infection.

#### ***Applications***

This therapeutic peptide would offer clinicians and patients an alternative/adjunct treatment option for HIV infection in those cases where patients are either intolerant to available agents or have developed virologic failure because of incomplete viral suppression or drug-resistant strains.

#### ***Market***

More than 22 million people have died of the acquired immunodeficiency syndrome (AIDS) and the condition has in one generation become the most devastating and persistent epidemic in recorded history. Although several combination regimens targeting enzymes that drive the infection have considerable anti-viral activity, many patients are now either intolerant of these agents or have developed drug-resistant virus strains. The development of a new class of anti-retroviral compounds with different mechanisms of action and toxicity profiles is therefore an important goal. The market for antiretroviral drugs is reported to increase from \$7.1 billion in 2005 to \$10.6 billion by 2015, as new anti-retrovirals are launched and the number of HIV-positive people increases.

#### ***IP Position***

Provisional patent application pending.

#### ***Commercialisation***

We seek a partner to fund further development of this technology through to Proof-of-Concept stages.

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## ***D. Software***

# 1. Automated Electrophysiological Substrate Mapping & Data Analysis

## Summary

Software system to create rapid, automatic-capture-and-display spatial maps by recording, identifying and cataloguing real-time electrophysiological cardiac beats and synthesizing beat detection, classification, analysis and substrate mapping. An automated digital assistant for EP surgery to locate electro-physiological problems, map them and eliminate them.

Dr Pramesh Kovoor, Network Director Cardiac Services and his team have developed this technology based on their clinical practice.

## The Technology

This patented software system is a unique 'digital-assistant' for current EP mapping technologies, allowing them to fully utilize all EP data collected from their sensors on every beat, rather than manual sequential data-collection from only selected beats. The digital-assistant makes EP procedures faster and easier by creating rapid, automatic capture-and-display spatial maps. Through comprehensive recording, identification and cataloguing of real-time EP cardiac beats, the system automatically synthesises beat detection, classification and referencing, analysis and multi-dimensional colored substrate mapping, adding a new dimension in speed and accuracy of EP mapping for clinicians.

## Benefits

The technology can be applied as a digital assistant to existing EP mapping systems or incorporated into new developmental systems. It can be engineered for compatibility with the following EP monitoring systems:

Magnetic [e.g. NOGA™ or CARTO™ systems (BioSense-Webster)]

ultrasound [eg. RPM (EP Medsystems-Boston Scientific)]

impedance [eg. EnSite NavX™ (Endocardial Solutions) or Localisa™ (Medtronic)]

## **Market**

The Atrial Fibrillation (AF) related market, in particular, is predicted to grow to US\$4.9 billion by 2010. Sales of non-drug AF products through the year 2010 are expected to increase by 23% annually to nearly \$3.8 billion (\$2.1 billion in core therapies) as the new technologies are gradually refined and adopted. Market analysts attribute much of the growth to emerging options assisted by enabling adjunctive technologies, such as infrared imaging and advanced 3-D real-time mapping.

## **IP Position**

A Provisional Patent application was filed in 2004 and is fully owned by Sydney West Area Health Service.

## **Commercialisation**

We seek a partner to license our technology for integration into their existing EP mapping technology. The licensee may partner with our clinical professionals for further research and development through clinical trials, taking advantage of their extensive experience in clinical EP.

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## 2. Software Risk Calculator HRT and Cancer

### Summary

A software based risk calculator which is able to estimate HRT use and cancer risk has been developed by Prof John Boyages and colleagues at the NSW Breast Cancer Institute, SWAHS. This software enables rapid assessment of the likelihood of a patient's susceptibility to breast cancer.

### Market

This technology meets an unmet need in the clinical environment to guide medical professionals in the most appropriate use of HRT.

### Benefit

The prediction of the likelihood of an individual developing breast cancer has wide application to all medical professionals dealing with women using HRT.

### Investment Brief

<b>Industry:</b>	Medical Software
<b>Proposed Business:</b>	Sophisticated software-based calculator able to estimate an individual's breast cancer risk for any woman of any nationality
<b>Team:</b>	Prof John Boyages NSW Breast Cancer Institute, SWAHS (02) 9845 8490 johnb@bci.org.au  Dr Nathan J Coombs NSW Breast Cancer Institute, SWAHS (02) 9845 8490 davidr@westgate.wh.usyd.edu.au

## ***Business Description***

A software-based risk calculator which is able to estimate HRT use and breast cancer risk. It is intended for use by general practitioners, gynaecologists, breast surgeons and individual women and women's groups. The calculator applies published HRT relative risk data to local breast cancer incidence data to provide an individual's breast cancer risk. This technique and methodology is applicable to any population worldwide allowing calculation of a woman's absolute breast cancer risk and estimating the additional risk for that woman with different formulations and duration of HRT use.

## ***Value Proposition***

The calculator would assist many consultations with women who may be concerned regarding their perceived additional breast cancer risk from HRT or family history and enable clinicians to provide individualized care to women. There is currently no other product on the market that is able to predict breast cancer risk to HRT users.

## ***Potential Market Applications of the Technology***

Breast cancer is the second leading cause of cancer deaths in women today (after lung cancer) and is the most common cancer among women, excluding non-melanoma skin cancers. According to the World Health Organization, more than 1.2 million people will be diagnosed with breast cancer this year worldwide. The American Cancer Society estimated that in 2005, approximately 211,240 women in the United States would be diagnosed with invasive breast cancer (Stages I-IV). The chance of developing invasive breast cancer during a woman's lifetime is approximately 1 in 7 (13.4%). The calculator is intended for use by general practitioners, gynaecologists, breast surgeons, breast cancer services, and public hospitals.

## ***Competitors***

To our knowledge there is no previous invention which uses dotNET technology to display a HRT Calculator based on the life time risk of breast cancer.

### *Sustainable Advantage*

Both inventors have extensive experience in the diagnosis and treatment of breast cancer and hold important positions in the NSW Breast Cancer Institute. They have access to a large pool of patients and there is international interest for the development/testing of the calculator.

### *Status of Intellectual Property*

An Australian provisional patent “Determining the risk of breast cancer for a woman”, # 2005901619, was filed on April 1, 2005 by Sydney West Area Health Service (SWAHS).

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