



GALVANI: A novel wireless power solution for artificial hearts

Taking our inspiration from the 18th Century Italian scientist, Luigi Galvani of Bologna, who pioneered the field of bioelectromagnetics, **the goal of Galvani BioElectric is to be the leading innovator in wireless power supply for implantable medical devices.**

Galvani will be the leading wireless power technology for a new generation of mechanical circulatory support systems including Left Ventricular Assist Devices (LVADs) and Total Artificial Hearts (TAHs). Our technology expands the realm of what is possible.

Heart Failure: The Challenge

Heart failure is a major global public health challenge. The prevalence of heart failure is increasing with projected annual costs in North America and Europe growing from \$60bn to \$140bn by 2030. Whilst many effective therapies exist options for end stage drug refractory heart failure are limited with heart transplantation an option for selected patients. Of the 140,000 patients in North America and Europe potentially eligible for heart transplantation a limited donor supply restricts availability to less than 4000 patients annually. In recent years donor availability has plateaued. Left Ventricular Assist Devices (LVADs) are used as a bridge to transplantation or increasingly as destination therapy. They significantly improve survival and quality of life for patients with advanced heart failure. However, these devices require a power driveline that passes through the skin to an external power supply which frequently becomes infected. One in five patients will develop driveline infection within six months of LVAD implantation. With more prolonged LVAD use in destination therapy driveline infection is an increasing problem, with a high (30%) mortality within one year.

Addressing Driveline Infection

Transdermal wireless power transfer (WPT) has been proposed as a solution to driveline infection. Traditional WPT systems have a rigid bulky receiver coil and require precise positioning of the transmission coil. High LVAD power demand (5-40W) leads to dermal (skin) overheating between the coils. Developed by a partnership of cardiologists and engineers Galvani's technology addresses these problems using thin flexible receiving coils implanted several centimetres from the skin. This higher degree of physical separation, while maintaining high efficiency, is possible due to our patented technology. A novel pulsed transmission waveform and hybrid proprietary coil architecture optimises power transmission. These measures mitigate dermal heating by allowing tissue cooling using blood perfusion during idle periods between energy transfer pulses. Thus the body's natural cooling system is used to eliminate problematic skin heating. With Galvani it is thus possible to transmit high power more efficiently with positional freedom. Integrated wireless data transfer allows continuous haemodynamic monitoring and device optimization. Galvani technology will

eliminate costly driveline related hospitalisations and improve patient quality of life. LVAD implant lifetime will be extended, an essential consideration with the growing trend towards destination therapy.

The target LVAD market continues to grow and with improvements in technology a total artificial heart solution is expected to be in clinical trials by 2025. Galvani is well positioned to address this growing market. Galvani's wireless power can be applied to any high demand medical devices that need mobility and a simplified charging experience.

Product Development and Partnering Strategy

The Galvani proprietary platform technology has been designed to ensure compatibility with all LVAD manufacturers. Partnering with leading medical device companies during design, preclinical and clinical stages will ensure successful system integration and regulatory compliance. Galvani's growing portfolio of proprietary IP and know-how will be licensed to medical device companies.

IP status

Patents have been filed in Europe, USA, China and Canada. Galvani is committed to protecting its IP and know-how.

<https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2017021846&tab=FAMILY>

UU technology transfer office and HSC Innovations will engage with future commercial partners.

Funding to date

This work has been supported to date by Ulster University technology transfer office and HSC Innovations, and the following grant funding from Invest NI and Heart Research UK.

Next Steps

Currently Galvani is in pre-incorporation stage. The team is working with the UU technology transfer office to establish a spin out company within the next six months. Galvani will leverage existing commercial relationships with medical device companies to advance current collaborative R&D programmes.

Galvani's intention is to raise significant seed investment round involving local and specialist medtech investors. This will grow the engineering, clinical and commercial elements of the projects within the company. Galvani will also leverage local and European funding for these activities.

Our ambition is to have Galvani progress from our current preclinical programme to clinical trials with major medical device manufacturers in three years.

To deliver this we will expand our bioengineering and management team. We will establish a pilot manufacturing facility.

The Team

Engineering and Clinical

Omar Escalona: Professor in the School of Engineering and a member of the Engineering Research Institute, Ulster University where he is Director of the Centre for Advanced Cardiovascular Research. Extensive experience in connected health wearables, atrial fibrillation, physiological monitoring solutions.

David McEneaney: Consultant Cardiologist with interest in device implantation. Twenty years experience in clinical/academic/commercial collaborative research. Multiple patents held in the areas of medical devices, novel cardiac and renal biomarkers.

Commercial

Vincent Farrelly: twenty years experience in commercialization of innovative products and proprietary technologies in corporate, public & start ups. MBA, MSc

Robert Perryman: fifteen years experience in MedTech company development. This includes fundraising, product development & manufacturing and US Sales & Marketing. PhD MBA

Early Career Researchers (ECR)

ECR (Clinical): Dr Alicjia Jasinska-Piadlo, has clinical expertise in advanced heart failure therapies including drug therapy, device therapy and heart transplantation assessment. Academically affiliated to Ulster University and Craigavon Area Hospital (Cardiac Research Unit).

ECR (Engineering): Dr Mohammad Karim, is a Post-doctoral Research Associate in the TWESMI Project at UU; funded by Heart Research UK, with expertise on computer modelling of skin tissue thermal perfusion profile, due to transdermal RF energy power link, using COMSOL Multiphysics.

Scientific Advisory Board

James McLaughlin: Professor and Director of the Nanotechnology and Integrated Bioengineering Centre - NIBEC at Ulster University. He has attracted over £55m of funding to establish multiple research programmes coordinated in the Engineering Research Institute (ERI), with over eighty researchers carrying out both basic and applied research. He has been awarded funding from EPSRC, Wellcome Trust, EU, NSF, DOH, DEL, HEA, Leverhulme Trust, RDA's and various funding bodies. He has been involved in multiple successful university spin out and spin in companies including Intelesens.

Dr Alastair Gray: Consultant Cardiologist with interest in advanced heart failure and device implantation. He has been involved in several global clinical trials and in the development of a pioneering implantable monitor.