



29th March 2011

Champagne corks fly as Lachesis-funded Nottingham company gains FDA approval for unique fetal monitoring device

Carl Barratt, Managing Director of Monica Healthcare Ltd is celebrating after winning US approval to market their unique fetal heart monitoring device in the USA.



Pictured (left to right): Prof Barrie Hayes Gill (Research Director), Dr Jean Francois Pieri (Technical Director), Dr Terence Martin (Sales & Marketing Director), Dr Carl Barratt (Managing Director)

The Monica AN24 is a wireless fetal-maternal monitor, the first of its type in the world. It measures the heart rate of the unborn baby, and helps identify potential problems before and during the birth process. Existing monitors measure mechanical signals, i.e. the mechanical movement of the fetal heart whereas the Monica AN24 device measures the tiny electrical signals from the fetal heart, and separates them from the much stronger signals from the mother's heart. The system is a very small wearable wireless device, rather than a large bedside monitor. The key advantage is the wireless aspect; the patient no longer has to stay on the bed whilst being monitored. Through the clinical trials, it has proved to be more accurate, working very well on obese mothers, an area where existing technology has had problems. The Monica AN24 also requires less intervention, so that the midwives do not have to move the transducers in the same way they do for current technologies. This makes the monitoring process easier for them and for the Mums.

The FDA is the regulatory body for all healthcare products in the USA and has responsibility for regulating their manufacturing, marketing and distribution.

Dr Carl Barratt (Managing Director) of Monica Healthcare, said: “Navigating the FDA process was by far the most challenging regulatory process we have been through to date. The FDA use dedicated specialist teams for reviewing submissions, and have very thorough requirements which have to be met to gain product release. However the FDA has proven to be very helpful throughout the process and now that 510k approval has been achieved, it provides further solid validation of the product and so is a very positive step forward.”

Monica was born out of research at the University of Nottingham’s School of Electrical and Electronic Engineering, and the Department of Obstetrics and Gynaecology, over a period of about 20 years.

“In 2005 we were able to raise sufficient finance to incorporate the company. At a time when we had very little experience in starting and managing a company, Lachesis were prepared to back us. The Lachesis Fund, which is 'part-financed by the European Regional Development Fund', helped with the initial financing of Monica Healthcare. There were very few equity organisations able to offer assistance at that time. Lachesis filled the funding gap firstly, and secondly, they added value to the company in the appointment of a valuable board member”, said Barratt.

The Lachesis Fund is financed by the East Midlands Development Agency (*emda*) and the European Regional Development Fund (ERDF). Early intervention by the fund helped with a Pathfinder award to investigate freedom to operate of the initial patent, which is still owned by Monica. Later, Lachesis took a lead role in the first round funding along with Catapult, and contributions from the management team, amounting to a total investment round of £500k.

When the company required additional finance to support its efforts to get approval to launch on the US market, Lachesis supported the business again. “In 2009 and 2010, we went to a number of potential external investors and after carrying out extensive due diligence at this point, Partnerships UK and other valued investors came on board,” said Carl. After experiencing and overcoming a lot of hurdles in the early stages, including putting a quality management system into place, the company has gone from strength to strength.

There is a very strong regional focus to the company’s operations. Says Carl: “We started the company with 2 full time staff and 2 part time people we now employ 10 people at our offices in BioCity. The monitor itself is built by a specialist manufacturer in Derby, and once we had proven the product through clinical trials, we got a lot of early adopter interest in using the system for feasibility studies, which led us to being able to sign distributors to sell in the European Union. This enabled us to focus on what was necessary for broader market adoption. The first product we got to the

market had a research angle to it rather than a clinical angle. Through the process of getting the product to the market as soon as we could, we learned what was needed in order to generate more traction in clinical markets, a really valuable learning experience.”

The Monica AN24 can be used in different clinical settings – in labour and delivery (L&D) and earlier in the pregnancy, in an ante-natal setting. Talking about the US market, Barratt commented; “For L&D, the device is being distributed in the USA through US company Glenveigh Medical LLC, who were chosen from a number of potential distribution partners. The Glenveigh team have extensive experience in this field and in introducing new and innovative products to the market. They have a particular focus on L&D and have complementary products already on the market.”

David Wallace, Director of Innovation at East Midlands Development Agency (*emda*), which manages the fund, said: “This is exactly the kind of project that the Lachesis Fund was set up to support. The fetal monitor that Monica Healthcare has developed is an innovative and exciting new product which I’m sure will be very successful and help to significantly improve prenatal healthcare.”

When asked what the next steps for Monica would be – Barratt explained they would be “to overcome the remaining regulatory hurdles so that we can deliver the product in the USA, China and Japan and to establish ourselves as a mainstream clinical provider of fetal monitoring products.”

Monica is building on its strong roots in the region, and looks set to be popping some more champagne corks when its first sales in the USA begin in the coming months!

ENDS

Notes to editors

Monica Healthcare

Monica Healthcare is developing a series of innovative wearable devices that will use wireless technologies to facilitate globally accessible obstetric services in the home and hospital.

Monica Healthcare Ltd was formed in May 2005 and was the culmination of 15 years of research at the School of Electrical and Electronic Engineering and the School of Human Development at The University of Nottingham, UK.

The patented technology is based on the acquisition of electro-physiological signals that can be passively detected by electrodes positioned on the maternal abdomen. From these signals a number of a parameters including fetal position, fetal heart rate, maternal heart rate, uterine activity, gross fetal movements and parameters describing Fetal ECG morphology can be extracted, in real time, and over an extended period of time.

The Lachesis Fund

The Lachesis Fund invests in spin out companies emerging from our partner Universities (De Montfort University, University of Derby, Loughborough University, University of Leicester, University of Lincoln, University of Northampton, University of Nottingham and Nottingham Trent University). Investments range in size from £25K to £250K.

Lachesis is a £10M fund, seeking to fill the 'seed-corn' funding gap that exists for very early technologies in the higher education sector and is part-financed by the European Regional Development Fund (ERDF) and the East Midlands Development Agency (*emda*).

Investments from the fund will help the commercialisation of promising University research by starting a new business, leveraging in co-investment and furthering the enterprise culture within the partner institutions.

Investments support projects in various ways: setting up new businesses, securing of commercial staff, enhancing and verifying intellectual property, prototype development, market research and business plan preparation.

Catapult Venture Managers

Catapult specialises in providing Equity Capital for businesses requiring between £200k and £2m.

Catapult provides a full range funding requirement from early stage, development capital to MBO/MBIs. Since 1999 we have invested in over 65 companies, providing initial and further follow on requirements. Our experienced team of seven Executives and two Non Executive Directors have over 100 years of VC experience between them.

University of Nottingham

Numerous small and medium businesses have benefited from the skills and facilities at The University of Nottingham.

SMEs often employ our students on placements or as part of a knowledge transfer partnership, others use the free service from the Centre for Career Development or employ our consultants on research projects to increase their competitive edge.

Enterprise and Innovation

At the Institute for Enterprise and Innovation (UNIEI) we work closely with SMEs to identify opportunities to work together, focusing on the development of enterprise and entrepreneurial skills as well as the commercialisation of research.

Alternatively, take a look at the Ingenuity Gateway - the first stop for SME business leaders to join networking events, sign up for workshops, or just generally get in touch. We'd be delighted to hear from you.

Partnerships UK



Partnerships UK (PUK) is a public private partnership which has a unique public sector mission: to support and accelerate the delivery of infrastructure renewal, high quality public services and the efficient use of public assets through better and stronger partnerships between the public and private sectors.

BioCity

BioCity Nottingham is one of Europe's largest bioscience incubators. Launched in 2003, the 129,000 sq ft award winning site currently hosts nearly 70 companies and over 525 employees.

The purpose of BioCity Nottingham is to provide a home for developing biotechnology and healthcare companies, with accommodation that is able to respond to a company's requirements by offering small highly flexible laboratory and office units, and grow-on space. It is able to cater for companies from 1 to about 80 employees.

By using flexible lab and office leasing arrangements, a company's growth requirements can be easily accommodated and it is the ideal solution for many types of ventures.

About ERDF nationally

The ERDF Programme aims to strengthen economic and social cohesion in the European Union by supporting regional economic development.

The ERDF objectives for England are:

- Promoting innovation and knowledge transfer
- Stimulating enterprise and supporting successful business
- Ensuring sustainable development, production and consumption
- Building sustainable communities
- Improving accessibility and connectivity (for Cornwall and the Isles of Scilly only - as part of their Convergence Programme).

A Programme Monitoring Committee consisting of regional stakeholders such as Government Offices, RDAs, Regional Assemblies, Local Authorities, Sub-regional Partnerships, Higher Education Institutions, Trade Unions, and the private and voluntary sectors will monitor and oversee programme implementation in each region.

For more information on ERDF funding generally, please visit www.communities.gov.uk/citiesandregions/european or http://ec.europa.eu/regional_policy/funds/feder/index_en.htm

About ERDF in the East Midlands

The East Midlands is eligible for €268.5m between 2007 and 2013, which when combined with match funding, provides a programme value of approximately €537m - a significant investment in the economic development of the region.

The East Midlands qualifies as a competitiveness and employment region under the EU's Cohesion Policy, which aims to meet the EU Lisbon objective to become 'the most competitive and dynamic knowledge based economy in the world, capable of sustainable economic growth with more and better jobs and greater social inclusion.'

East Midlands Development Agency (*emda*) is responsible for the programme management and delivery of the region's 2007-13 ERDF Competitiveness Programme. The responsibility for ERDF programme management was transferred from the Government Office for the East Midlands (GOEM) to *emda* following a decision by the UK Government to seek greater alignment between ERDF and regional strategies and funding streams. The 2007-13 ERDF Programme is therefore set firmly within the framework of the Regional Economic Strategy.

A Programme Monitoring Committee, chaired by the Regional Director of Government Office for the East Midlands (GOEM), guides the strategic direction of the programme and works closely with *emda*.

To find out more about ERDF, the region's strategy for delivering the funds, how to apply for funding and how the programme is managed, please visit www.eastmidlandserdf.org.uk

About *emda*

East Midlands Development Agency (*emda*) is one of nine Regional Development Agencies (RDAs) in England, set up in 1999 to bring a regional focus to economic development.

Independent evaluation shows that *emda* has:

- Had a significant impact on the region's economy
- Generated economic benefits that substantially outweigh its overall costs
- Put back over £9 of economic output (or GVA) into the regional economy for every £1 it spends
- Produced more than £1 billion in economic benefits per year
- A wider impact on people, places and businesses in the East Midlands that cannot be captured by figures alone.

The Coalition Government announced in June 2010 that RDAs will cease to exist beyond March 2012 and that economic development and regeneration will be led by Local Enterprise Partnerships (LEPs), where locally-elected leaders will work with businesses.

emda is working closely with Government and partners in the region to manage the transition of its responsibilities and ensure that business has a voice in new arrangements as they develop. During this transition period, our main task remains to support economic recovery and future growth in the East Midlands.

For more details visit www.emda.org.uk