

**Dublin 13<sup>th</sup> April 2004**

## **BiancaMed Secures Major Investment and Licenses Sleep Apnoea Detection System**

### **- BiancaMed locates to NovaUCD, UCD's Innovation and Technology Transfer Centre**

Irish medical technology company, BiancaMed, a spin-off from University College Dublin's (UCD) Department of Electronic and Electrical Engineering, has announced a strategic financial investment from ResMed, Inc. ([www.resmed.com](http://www.resmed.com)), a leading U.S.-based respiratory medical device manufacturer. In addition, BiancaMed has licensed its proprietary technology for the screening of sleep disordered breathing to Del Mar Reynolds ([www.delmarreynolds.com](http://www.delmarreynolds.com)). Del Mar Reynolds is a leading supplier of hospital-based electrocardiogram (ECG) Holter systems in the U.S. market, and also has leading market shares in the United Kingdom and Germany.

BiancaMed, which is located in NovaUCD, UCD's Innovation and Technology Transfer Centre, has recently launched its first product, *SleepScreen*, in collaboration with Del Mar Reynolds and ResMed. *SleepScreen* allows a standard outpatient electrocardiogram to be used to identify people with sleep apnoea. This product was launched March 7<sup>th</sup> 2004 at the Annual Scientific Session of the American College of Cardiology, with an attendance in excess of 25,000 delegates.

BiancaMed aims to capitalise on the increased need for intelligent computer-based analysis of medical signals and, in particular, on market needs for new diagnostic and classification analysis in the fields of sleep medicine and cardiology.

Sleep disordered breathing (SDB) is a cardio-respiratory disorder characterised by brief interruptions of breathing during sleep. Often the sufferer has no recollection of these sleep interruptions that can occur hundreds of times in a night. Important health implications of sleep apnoea include its impact on the heart (increased frequency of developing hypertension, heart failure, and coronary arterial disease), as well as increased frequency of fatal motor vehicle accidents due to sleepiness, and many quality-of-life issues.

It is estimated that there are 30 million sleep disordered breathing sufferers in the USA alone, and that 85% of these are undiagnosed. Similar numbers are estimated in Europe. Given appropriate and timely diagnosis, the outlook for sufferers is encouraging, since an effective therapy exists.

From a public health perspective, one of the most significant issues related to sleep disordered breathing is how to provide cost-effective and accurate diagnosis. Currently, diagnosis typically requires an overnight stay in a dedicated sleep laboratory, which is costly (€700+); and in many laboratories the waiting time for a study exceeds six months.

Recent research has also shown that SDB is strongly associated with heart disease, with more than 30% of people with cardiovascular problems also having sleep apnoea.

Recognising the need for low-cost assessment of sleep apnoea and the strong association of SDB with heart disease, BiancaMed has developed technology which screens for SDB using only the electrical signal of the heart, the electrocardiogram (ECG). The ECG is a useful signal to use, since it is familiar to cardiorespiratory clinicians and is already routinely gathered on an outpatient basis using a device called a 24-hour Holter ECG monitor.

Using BiancaMed's apnoea detection system, a patient sleeps overnight at home and wears a Holter monitor (with three electrodes attached to his/her chest). The following morning, the overnight ECG signals are downloaded onto a PC for analysis using BiancaMed's patented algorithm. The algorithm automatically identifies the occurrences of the brief interruptions of breathing. It also calculates the average number of breathing interruptions per hour, which provides a measure of the severity of the disease. By allowing the study to be performed at home, BiancaMed's technology significantly reduces both the cost in detecting the disease and the waiting time for a study.

BiancaMed has licensed this technology to Del Mar Reynolds, a global market leader in ECG Holter monitoring. BiancaMed launched its initial product, *SleepScreen*, which incorporates this technology at the recent American College of Cardiology Conference held in New Orleans. *SleepScreen* which was jointly developed with Del Mar Reynolds allows a standard outpatient ECG to be used to identify people with sleep apnoea. This then allows cardiologists to refer their patients to a sleep disorders clinic for further diagnosis or treatment of the SDB.

The *SleepScreen* system is integrated with Del Mar Reynolds' *LifeScreen* Holter analysis system. This provides cardiologists a complete picture of all abnormal heart rhythms experienced during sleep, some of which may be the precursor to a heart attack or even sudden cardiac death.

Dr Philip de Chazal and Dr Conor Heneghan developed BiancaMed's apnoea diagnostic technology during 2001/2002 from research undertaken in UCD's Department of Electronic and Electrical Engineering. The pair founded BiancaMed during 2002 as a spin-off company.

The US is the primary market for sleep disorders devices but Europe is starting to catch up as awareness of sleep disorders increases. There are approximately 3000 sleep centres / hospital sleep units in the US and it is estimated that they perform over one million in-laboratory overnight diagnostic tests per year, generating in excess of US\$1.2 billion in revenue annually. Market saturation is a long way off, as it is estimated that only 15% of sleep apnoea sufferers in the US have been diagnosed, with similar or lesser numbers elsewhere in the developed world.

The US sales of diagnostic equipment for sleep disorders in 2003 were \$90 million, growing at 6%.

Speaking on the ResMed investment, Dr Philip de Chazal, BiancaMed's Chief Technology Officer, said, "We are delighted to have ResMed as a strategic investor in BiancaMed. In addition to the financial investment, ResMed provides a wealth of experience and contacts in the area of sleep disorders which are proving invaluable in getting *SleepScreen* to the market."

Speaking about the recent successes for BiancaMed, Dr Conor Heneghan, BiancaMed's Chief Scientific Officer, said "Despite spending nearly one-third of our lives asleep, the role of sleep and sleep disorders in overall health is still relatively unknown. BiancaMed is focused on providing simple and accurate diagnostic tools which can facilitate increased understanding in the area of sleep and sleep disorders"

Speaking on *SleepScreen*, Dr Philip de Chazal, said "*SleepScreen* scans a patient's night-time ECG recording for the evidence of sleep disordered breathing in just a few seconds. The same task for a sleep technologist analysing the signals recorded in a sleep laboratory test can often take an hour or two."

Dr Pat Frain, Director of NovaUCD, said, "BiancaMed is a prime example of the NovaUCD approach to spin-off activity at UCD, i.e. Innovation through Co-operation. Commercial partners such as Del Mar Reynolds help to ground high quality research in a commercially realistic context. We are delighted to welcome BiancaMed to the community of entrepreneurs at NovaUCD."

NovaUCD is University College Dublin's EUR10 million Innovation and Technology Transfer Centre. This purpose-built centre, which has been funded through a unique public-private partnership, nurtures new technology and knowledge-intensive enterprises. NovaUCD has over 40 incubation units and provides innovators and entrepreneurs with the necessary support and knowledge to take their ideas from proof of principle to commercial success.

## **ENDS**

XX March 2004

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For further information on ResMed visit [www.resmed.com](http://www.resmed.com)

For further information on Del Mar Reynolds visit [www.delmarreynolds.com](http://www.delmarreynolds.com) or [www.delmarmedical.com](http://www.delmarmedical.com)

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## **Editors Notes:**

**ResMed**, formed in 1989 and head quartered in California (USA) is a leading developer, manufacturer, and marketer of medical equipment for the diagnosis and treatment of sleep-disordered breathing (SDB).. ResMed operates through direct offices in the United States, the United Kingdom, Switzerland, Sweden, Spain, Singapore, New Zealand, the Netherlands, Malaysia, Japan, Hong Kong, Germany, France, Finland, Australia, and Austria, and through a network of distributors in more than 60 other countries.

**Del Mar Reynolds** was formed as a result of a merger between Reynolds Medical and Del Mar Medical. This merger formed the world's largest manufacturer of ECG Holter systems. The combined product range encompasses resting ECG, stress testing, Holter, event monitoring, ambulatory BP and Information Management systems.

## **BiancaMed's Founders:**

Dr Conor Heneghan is BiancaMed's Chief Scientific Officer with responsibility for identifying clinical market opportunities and managing external research interactions. He is also a senior lecturer in UCD's Department of Electronic and Electrical Engineering. Prior to joining UCD, he was Director of Tele-Informatics at The New York Eye and Ear Infirmary and a post-doctoral

researcher at Boston University. He completed his doctoral studies at Columbia University. His previous research work has included analysis of electrocardiograms and neural signals. His unique skills are in the area of signal analysis and feature detection.

Dr Philip de Chazal is BiancaMed's Chief Technology Officer and has prime responsibility for design and implementation of biomedical signal processing algorithms and system architecture. He was a research fellow in UCD's Department of Electronic and Electrical Engineering from 2000-2003. Prior to joining UCD, Dr de Chazal worked at Medcare Systems (Sydney, Australia), subsequent to completing his PhD at the University of New South Wales. He has particular expertise in signal processing and pattern recognition for biomedical applications specialising in the analysis of electrocardiograms.