

Agenda Item 135/08

Public Board Meeting, 21 August 2008

<u>Ear Scaffold</u> - Proposal to enter Into a Joint Venture on the Development of Ear Scaffold Technology

Presented by: Graham Ramsay, Medical Director

Introduction

During the course of their employment with the Trust Mr Norbert Kang, consultant Plastic Surgeon and Mr David Gavin, Technician, (the Inventors) conceived and developed an ear scaffold device. This device is now the subject of a commercial endeavour in line with the Department Of Health guidance on the Use of Companies in Income Generation by the NHS. On 28 September 2006 the Inventors confirmed assignment to the Trust of all Intellectual Property Rights in, and Know-How related to the Invention, to the Trust.

The process has now reached the stage where the Trust needs to enter into a formal legal agreement with Health Enterprise East (HEE) Ltd the local Enterprise Hub established by the DoH whose main purpose is to provide an intellectual property management service to NHS Trusts and Primary Care Trusts. A Hub provides this service over a geographical region administered by a Regional Development Agency.

It is anticipated that, once the required processes have been completed and the invention becomes commercially marketed the Trust will benefit from shares in the company. It is anticipated that that stock market flotation will take 2-3 years.

Background

In 2006 the Invention received first prize in the annual innovations competition and was awarded £3k to progress the invention through its development and patent processes. An additional sum of £15k was provided by HEE to support the Inventors with this activity.

Mr Kang and HEE are currently finalising and securing world wide patents pursuing the registration of patents for the invention.

The project has progressed from the Inventors' initial thoughts and sketches to a professionally machined prototype applicator and scaffolds in both spring steel and nitinol (a super-elastic metal alloy of nickel & titanium). Some testing has taken place on animal cadaver tissue.

The role of HEE is to help the Trust and its employees through the complex processes of forming a successful company and the development of the technology. A business plan has been prepared and a proof of concept grant provided by EEDA to enable a marketing study for the technology to be undertaken.

Current Position

Following meetings in 2006 and discussions with the former Finance and Performance Committee of the Trust Board and then at Part 2 meetings of the Board, the project has reached the stage where the Trust Board needs to make some formal decisions on the future role and contribution it will make to enabling this project to move forward. A spin out company has been established however the Trust needs to take a view on its role within the company as well as the level of equity share it will hold. At its meeting on 26th June 2008, the Board, in Part 2 (given the commercially sensitive nature of the discussion) considered an update paper on the Ear Scaffold Invention. At the conclusion of the discussion it was agreed that Colin Gordon and Stuart Lacey would meet with Norbet Kang and relevant colleagues to discuss the concept in more detail, a proposed business plan and the equity share arrangements. This meeting took place on 1st July.

Following very positive discussions at the 1st July meeting, during which the whole range of relevant issues were discussed, the Board now needs to consider a number of issues and make decisions on whether to proceed with further involvement with the project.

First the Board needs to consider the equity share that it should hold in the company. This will ultimately determine the level of financial benefit the Trust could achieve in the future were it to sell its share. Given the level of investment made by Mr Kang it is proposed that he has the greatest individual share with equal share going to the Trust and HEE. There is a proposal for a small percentage of shares to be allocated to other small investors and as management incentives.

There is currently a revenue sharing agreement in place between the Trust and the two inventors. Mr Kang has suggested that, given the level of equity it is proposed that he holds in the company, that he gives up his rights to this revenue sharing agreement. This is not the case for the second inventor and the Trust would have to honour this agreement in respect of this individual.

The Trust will need to enter into a formal legal position and sign Heads of Terms which ensured that all the interests of the Trust were protected. This document will need to be draw up between the legal teams.

Actions and Recommendations

The Board is asked to agree that:

- a) Equity shares in the proposed spinout company be split 45% to Norbet Kang, 22.5% to West Herts Trust, 22.5% to Health Enterprise East, 10% to other smaller investors and as an incentive option;
- b) Norbet Kang would relinquish his rights in respect of the revenue agreement;
- c) West Herts Trust would receive 70% of the revenue after HEE have taken revenue against receipted costs and their management fee. West Herts Trust would need to ensure the honouring of the distribution of any revenue gained to the second inventor who has not waved his rights to the revenue sharing agreement;
- d) The heads of terms agreement would be finalised ensuring at all times that the Trust were in no way disadvantaged or expectations placed upon it that impacted adversely on its statutory duties and obligations and,
- e) That as a minor share holder appropriate measures were contained within the heads of terms that ensured that West Herts Trust were not disadvantaged in relation to the conduct, decision making and governance of the proposed spinout company.

Subject to the Board's approval HEE will present a proposal to the Department of Health's Commercial Directorate in line with National Guidance on the establishment by NHS Trusts of companies of this nature.

It should be emphasised that the Trust is not being asked to make any financial contribution to the set up and development costs. The only contribution being asked of the Trust is to transfer the intellectual property, currently owned by the Trust to the spinout company. At the present time the intellectual property has very limited value. One estimate suggests the value is no more than approximately £40,000. Should the venture fail to proceed to full commercial status and begin to deliver a return on the investments made by HEE and Mr Kang there will be no financial exposure for the Trust.

Professor Graham Ramsay

Medical Director