

ASX Announcements

May, 1999

SHAREHOLDER UPDATE MAY 1999

Dear Shareholder,

Introduction

The Board of Optiscan is delighted to provide this status report to shareholders. In the period since the listing of Optiscan on the ASX in August 1997, significant progress has been made and many of the objectives of Optiscan set out in our prospectus have been achieved. Indeed, the purpose of this update is to highlight the significant developments that have taken place in the move toward commercialisation of our patented technology, i.e. the miniaturised confocal laser imaging microscope.

Key Developments

The last 18 months have resulted in the following key developments:

Optiscan has clearly established that its technology works and is well advanced in the development of the application of that technology in the medical diagnosis of various diseases (described further below).

Given the advanced stage of development of the various applications, Optiscan is now moving to discussions with potential distributors of our products in preparation for the commercial launching of a miniaturised confocal laser imaging microscope late next year. Interest has previously been expressed by a number of multi-national organisations and Optiscan has brought forward the timing of discussions with such organisations, due to the advanced stages of the development of the various applications.

Optiscan has received further confirmation of the strength of its patent protection, having recently resolved a second patent infringement claim, this time against Noran Instruments, a major American manufacturer of scientific instruments (for details, see below). This follows the earlier resolution of a patent infringement claim against Olympus Optical Co Limited, the largest optical instrument manufacturer in Japan.

Background

At the time of listing, Optiscan's primary focus was the further research and development of its patented optical fibre and laser technology.

While the Optiscan technology is in fact a platform technology with diverse applications, including medical, biological, materials analysis and surface topography, the research and development phase has concentrated on what Optiscan believes to be the more lucrative of the potential applications, that being medical diagnosis. This decision was based on the directors' belief that the confocal endomicroscope could become a general diagnostic device with large potential markets for a range of medical conditions, including burns and skin, bowel and cervical cancers.

The combination of fibre optics and laser technology in the unique and patented form of a miniature confocal microscope has enabled Optiscan:

to produce the world's first and only mobile confocal microscope system; and

to obtain, for the first time in medical diagnosis, immediate and non-invasive digital 3D images and sections of living cells in the human body.

Where conventional microscopes can only be used to examine excised tissue (i.e. biopsies), confocal microscopes can look at living tissue in 3D. However, conventional confocal microscopes are bulky and expensive. It is the ability of Optiscan to miniaturise the confocal microscope that is the key to Optiscan's future. The Optiscan confocal laser imaging microscope, like other confocal microscopes, can provide pin point focus (at up to 1,500 times magnification power). The advantage with the Optiscan system is that it produces sharper and higher resolution images than conventional optical microscopes and has the ability to miniaturise and make the microscope mobile. These features open up a whole new world of potential uses for the Optiscan product.

The Optiscan Products

As we know, Optiscan's technology works and the development of applications for various medical diagnoses is well advanced. Optiscan's first research confocal microscope, the benchtop F900e is already in use in many research institutions (for example, Royal Children's Hospital, Royal Prince Alfred Hospital, CSIRO, Monash University, Sydney University). The unit is compact, user friendly and cost competitive. It is one of several competitors in the world market for traditional confocal microscopes.

Following the benchtop F900e, Optiscan has developed a rigid endomicroscope. It is being used in human trials at a leading melanoma unit. The rigid endomicroscope is important because it is the forerunner for the hand held and flexible clinical versions. These instruments are without parallel in the world today and, because of the ease of their use and the ability to obtain immediate, non-invasive clinical results, have the potential to revolutionise medical diagnosis, including burns and skin, bowel and cervical cancers.

The Time Line for Further Product Development

Set out below is a chart highlighting the intended product development pipeline for each of the above products.

Targeted Areas

There is no doubt that medical diagnosis is the market that offers the greatest opportunity. Trends towards preventative medicine (particularly the early detection of cancer) are driven by the high costs attributable to late detection of disease. We believe Optiscan's technology offers government and medical authorities an opportunity to reduce this very significant drain on the healthcare budget, and to increase the longevity of those patients afflicted.

Optiscan's immediate target areas are skin melanomas, burns and colon and cervical cancers. In these areas, the medical facts speak for themselves. For example, melanomas kill over 1,000 Australians and 7,500 Americans per annum. Treatment costs attributable to late detection of melanomas are in excess of \$250 million per annum in Australia and over US\$1 billion in the USA. Further, there is a 98% chance of survival if melanomas are detected sufficiently early.

Similarly, for colon cancer 60,000 people per annum in the USA die from the disease and treatment costs are estimated to be in excess of US\$10 billion.

Traditionally, diagnosis often involves screening and biopsies. Biopsies are invasive and involve the surgical removal of tissue. By their very nature, they are restricted to small areas of tissue, risk infection and do not always produce immediate answers. Compare this to the use of Optiscan's hand held or flexible probes. A significantly broader examination could be taken of the relevant part of the body, in a safe, non-invasive manner with the opportunity of an immediate answer.

For Optiscan, the target customers and users of its hand held and flexible probes range across all areas of medicine including:

hospital and medical clinics;

pathology and radiology centres;

endoscopy centres;

dermatology clinics and medical centres;

women's health centres.

Patent Protection

Optiscan has always been confident that its patent protection (as outlined in our

1997 prospectus) is sound. In our opinion, this has been independently verified through the recent resolution of two patent infringement claims we have made in respect of our existing desktop confocal microscope. Noran Instruments, a major American manufacturer of scientific instruments, has agreed to pay a lump sum in respect of its infringement of Optiscan's patents. Further, Optiscan will also receive royalties on all further sales by Noran of desktop confocal microscopes that would otherwise fall within Optiscan's patent protection.

This is the second patent infringement claim that Optiscan has settled in respect of its existing desktop confocal microscope technology (both involving a lump sum payment and ongoing royalty payments). The first infringement claim was against Olympus Optical Co Limited, the largest optical instrument manufacturer in Japan.

Negotiations continue with at least 4 other manufacturers throughout the world in respect of their breach of Optiscan's patents. These discussions relate only to desktop confocal microscopes for general research use and do not relate in any way to Optiscan's unique endoscopic applications of the technology, which is Optiscan's key proprietary technology and business focus.

The Next Steps

So how is Optiscan moving its technology from the laboratory to the clinic? The answer to that question is relatively simple.

First, the interest in Optiscan's products has been such that prototypes (although not yet released as clinical products) are already in use in some leading burns and melanoma units in Australian hospitals.

Second, Optiscan's products have been designed and developed with the Australian, U.S. and European regulatory requirements in mind. Therefore, Optiscan does not anticipate difficulty in quickly obtaining regulatory approvals, especially for the use of the hand held probe as it is non-invasive.

Further, while Optiscan has regularly received enquiries from US, European and Japanese manufacturers and distributors of medical equipment, it has to date not pursued those enquiries in the belief that it was too early in the development phase to consider entering into an alliance. However, product development is now approaching the point of commercialisation. Optiscan is in the process of converting enquiries by distributors into preliminary discussions focusing on a strategic alliance for the commercial development and international distribution of Optiscan's clinical instruments and associated consumables. Optiscan is hopeful that it can, in the near future, announce the establishment of an alliance with a major multinational company for the distribution of its products.

While the Directors believe the high risk research and development is now behind us, and are therefore confident of the future success of the Optiscan products, there is obviously work still to be done. Optiscan's achievements in its first two years (proving that the technology works at a practical level and the success of the initial prototypes) is a major step forward in obtaining the goals outlined in this Shareholder Update.

Peter Delaney

Managing Director
Optiscan Imaging Limited

info@optiscan.com

[Back](#)