

ASX Announcements

20 April 2001

OPTISCAN IMAGING UPDATE

Dear Shareholder Welcome to the first Optiscan Shareholder Newsletter for 2001. As we expect this year to be a significant one for your company, it is our intention to provide you with regular shareholder updates. In this edition we will provide you with information about:

The company's strong financial position

The status of the FDA approval application for the Hand Held Scanner

The progress of commercialisation activities for the Hand Held Scanner and

The progress of other product development.

HALF YEARLY RESULTS

Shareholders will be aware that the company recently reported a consolidated loss of \$2.19 million for the six months ended December 31, 2000. The loss was in line with budget and compares to a loss of \$1.03 million in the previous corresponding period. The company is at an early and exciting stage of its development, and increased costs associated with the commercialisation of the Hand Held Scanner contributed to the result. Other significant factors affecting the result included:

Expenses relating to relocation to new premises including offices, manufacturing facility, warehouse and laboratories.

Fewer sales of older technology, research grade products.

Royalty income increased from \$234,000 to \$300,000 during the period.

Optiscan was also notified that it will receive an additional \$400 000 extension to the \$1.9 million grant from the Commonwealth Government's START Grant program.

Your directors believe that with a strong balance sheet, adequate cash reserves of more than \$9 million, and the well advanced status of the Hand Held Scanner's commercialisation phase, the company is in a strong position to move forward.

THE HAND HELD SCANNER (OPTISCAN "STRATUM")

We have now finalised the design and put in place the initial manufacturing capability for the commercial release of Optiscan's Hand-Held Scanner, to be marketed as the Optiscan "Stratum". The first production units are currently being manufactured at the company's Notting Hill, Victoria, administration and manufacturing site.

A growing list of applications has been investigated or clinically trialed over the past 12 months. These trials are critical in order to position the product for commercialisation. Dermatologists have shown great interest in the Hand Held Scanner, largely because of its wide range of potential applications. These include detecting:

skin cancer

psoriasis and inflammatory lesions

monitoring of cellular events related to therapies – eg. tumour reduction and drug distribution within cells

FDA APPROVAL PROCESS

As I outlined in our Annual Report and via a recent ASX announcement, Optiscan has taken all the necessary steps required to meet regulatory requirements for FDA approval. The process is taking longer than we anticipated, but this is not unusual. There has been regular communication with the FDA and recent requests by the FDA for information indicate that there are no major issues.

It is important to emphasise that despite the delays, the regulatory process is significantly less extensive for certain classes of medical devices than it is for most new pharmaceuticals. In particular, the Optiscan Stratum – mainly to be used for dermatology applications – faces the lowest regulatory barriers because:

it is not hazardous to operators or patients;

it is not an implantable device;

it does not come into contact with internal tissues; and

it does not make diagnostic decisions.

Our specialist FDA application consultants in the USA have asked the FDA to classify the Stratum as a Class 1 medical examination device. It is important to note that the FDA approval process is not impeding the company's current strategic focus. We are actively focussed on the first production run, existing and planned clinical trials and market development strategies while the FDA processes our application.

MARKETING

US Food and Drug Administration approval of the Optiscan Stratum will allow Optiscan to market and sell the product in the US, which has a population of 250 million. The company believes major US dermatology and cancer centres will be the primary target market for the Stratum and this will be our major focus over the next 1 to 2 years.

The initial marketing of the Stratum in the USA commenced late last year with our attendance at the American Society for Biological Therapies conference held in Seattle.

This proved to be an ideal setting to introduce our technology to America's leading clinical Oncologists and Therapists and our technology was met with a great deal of enthusiasm. We were able to compile an extensive and promising list of interested potential users and early adopters.

Following this conference, we attended the large Clinical Oncology Society of Australia meeting in December to introduce the technology to Australia's Oncology clinicians. This meeting allowed us to build a substantial database of prospective users and specialists within Australia.

The highlight of our efforts occurred in early March 2001 when we exhibited one of the Stratum units to a large and enthusiastic group of America's top Dermatologists at the American Academy of Dermatology meeting held in

Washington DC.

More than 10,000 Dermatologists and specialists attended the conference. Our presence enabled many of them to view the Stratum and reinforced the future role of Live Micro Imaging (LMI) in providing invaluable cellular information never before attainable. Importantly, we were able to make contact and begin dialogue with an additional 40 prospective U.S. distributors, who were also in attendance as exhibitors.

Further exhibitions of the Optiscan Stratum are planned this year including:

The Society for Investigative Dermatology, Washington DC, 9 - 13 May

The American Society for Clinical Oncology, San Francisco, 12 - 15 May

Digestive Disease Week, Atlanta , 20 - 23 May

International Photobiology Association, Vancouver, 5 - 9 June (Photodynamic Medicine)

American Academy of Dermatology, Anaheim, 28 July - 1 August

World Congress of Microcirculation, Sydney, 19-23 August

Australasian Digestive Disease Week, Sydney, 23 - 28 September

These exhibitions will highlight the Optiscan Stratum to a wide range of potential customers and distributors.

FURTHER CLINICAL TRIALS

There has been much interest among specialists in our technology, and this year Optiscan plans to launch several clinical trials to add to those established last year. These trials will not only serve to consolidate the existing applications of the Optiscan Stratum, but will pursue other applications of the platform technology, exploring issues like gastroenterology.

The Optiscan Stratum is currently being trialed at the Skin Centre in Benowa on the Gold Coast. Queensland has the highest incidence of melanoma in Australia. More than 2,000 people are diagnosed with melanoma in

Queensland each year and close to 200 people die each year from the disease. Preliminary results from the trial are promising and will be published later in the year.

THE FLEXIBLE SCANNER

At the same time as we are taking the Optiscan Stratum into clinical trials and commercial grade manufacturing we are separately developing a Flexible Scanner. Significant improvements have been made to the design of the Flexible Scanner, in particular in the further miniaturisation of the scanning mechanisms to enable internal examination of body cavities such as the colon and bowel. Testing of the Flexible Scanner in animals has been encouraging and we expect to construct advanced prototype scanners for clinical trials in humans later this year.

The Flexible Scanner's ability to enable internal microscopic examination of patients without the need for a biopsy has a wide range of potential applications in gastroenterology including the detection of: colon cancer, mouth cancer, gastric cancer, Barret's oesophagus, ulcerative colitis and cancer management.

FURTHER PRODUCT DEVELOPMENTS

As outlined in the Annual Report, the Hand Held Scanner (Optiscan Stratum) represents a platform, upon which other products will be developed. This year the company plans to develop uses for the Flexible Scanner, which will be followed by the development of new products for use in other organs of the body. These include various shaped, rigid and flexible probes for applications in the head and neck, for obstetrics and gynaecology, respiratory medicine and keyhole surgery.

ALLIANCES

Discussions continue with potential strategic allies and distribution partners. The outlook, as mentioned in the Annual Report, remains positive, particularly as our business model now includes technology relating to consumables (dye kits) and telemedicine. Sales of the dye kits which are required each time the Stratum is used are expected to be a significant source of ongoing revenues after commercialisation. Discussions with possible dye suppliers are continuing. However we do not plan to finalise any agreements until commercial production commences.

I hope you have found this shareholder newsletter informative. I will be writing to you with a further update in about three month's time.

Yours sincerely

Peter Delaney
Managing Director