

# Optiscan Imaging Limited

## Directors' Report

The Board of Directors of Optiscan Imaging Limited has pleasure in submitting its report in respect of the financial half-year ended 31 December 2000.

### Directors

The names and details of the directors in office during or since the end of the half-year are:

Professor Raymond Martin (Chairman)

Peter Delaney (Managing Director)

Professor Martin Harris (Director)

Dr Alan Finkel (Director)

All directors held their position as a director throughout the half-year and up to the date of this report.

### Principal Activities

The principal activities of the consolidated entity during the period were the development and manufacture of confocal microscopes and development of their applications in medical examination. There were no changes to the nature of these activities during the half-year.

### Results

The consolidated loss of the economic entity for the half year ended 31 December 2000 was \$2,193,723 (1999, \$1,031,826).

The increase in the loss compared to last year is a reflection of the company's continuing progress toward commercialisation. It is also consistent with the strategic planning of the company.

There are three predominant factors in the higher reported loss:

- Lower grant income as development phase concludes
- Increased investment in commercialisation of the new products
- Fewer sales of older technology, research grade products

During the December half-year, the final development phase of the flagship first clinical product, the hand held probe (now product-titled the "Stratum") was accelerated, and largely completed in October. As a consequence, the grant funding from the Government drew to a close upon completion of development, causing a comparative decline in grant revenue of \$450,000.

At the same time, the company has moved into a number of post development activities, including the first production runs of the Stratum Scanner, regulatory submissions, pre-

marketing activities, and involvement of the instrument in clinical trials. These new activities have broadened the company's cost base during the half-year.

Finally, all sales and marketing activity is now directed at the Stratum product, whereas early last year there were a number of sales of the research grade F900. As the company moves closer to releasing the new product range, sales of the research grade instrument become both less significant and less likely.

## **Review of Operations**

Operations during the half-year were primarily focused on the commercialisation phase of the Stratum probe. This product offers unique capabilities in imaging the skin of patients at the cellular level, without the need for surgical biopsy.

Commercialisation activity is focused on the fields of dermatology and oncology, in applications where biopsy free imaging of skin pathology is most desirable. These include skin cancers, inflammatory conditions such as psoriasis and eczema, and monitoring of cellular level events which occur in the skin during cancer therapy.

The key activities to this end include:

- Final development and early stage manufacturing of the Stratum
- Marketing and market development
- Ongoing Clinical trials in support of market development
- Regulatory submissions

### ***Final development and early stage manufacturing of the Stratum***

Optiscan relocated to new premises during October 2000 to establish facilities for manufacture of the Stratum. The plant offers scope for expansion to accommodate anticipated capacity requirements for the next several years. Presently, only small runs are being engaged to serve the requirements of market development and uptake by early adopters (see below).

### ***Marketing and market development***

Optiscan has launched into significant marketing activity of the Stratum Scanner, both locally and in the U.S.A. The key goals of this activity include:

- Raising the profile and awareness of the technology in the U.S. medical marketplace
- Targeting initial uptake with high profile, opinion-leading clinicians in the U.S.
- Securing a market development and distribution partnership with a large health care company established in the U.S.

Optiscan has initiated a steady schedule of attendance as an exhibitor at significant U.S. based medical conferences. This began in October 2000 and will continue throughout calendar 2001, including presence at the meetings of the American Academy of Dermatology (Washington), the Society for Investigative Dermatology (Washington), the American Clinical Oncology Society (San Francisco).

This will provide regular exposure to, and contact with, both potential distribution partners and important local clinicians.

### ***Ongoing Clinical trials in support of market development***

Uptake by the conservative medical marketplace is anticipated to remain modest in the short to medium term as the wider medical market place awaits the demonstration by leaders in the field of the benefits of the technology. As such, both the ongoing clinical trials and the work of early adopters of the Stratum have been, and will be, of critical importance in the rate of acceptance in the long term.

These activities are aimed primarily at the establishment of a large atlas of microscopic images of normal skin and skin lesions and their comparison with the pathologist's conventional view of surgical biopsy tissue. Publication of these results in internationally respected medical journals and also presentations by our clinical collaborators at key international conferences will then offer the most respected mechanism for raising awareness among the wider medical community.

Our Clinical liaisons in this endeavour include the Alfred Hospital (Melbourne), Sydney Melanoma Unit (Sydney), the Gold Coast Skin Centre and Gold Coast Hospital (Gold Coast, Australia), Gribbles pathology (Melbourne, Australia) and the University of Pittsburgh's Centre for Biologic Imaging.

***Regulatory submissions***

Optiscan's 510(k) submission to the U.S. Food and Drug Administration for approval to distribute the Stratum in the U.S.A. is pending. Optiscan is confident of a positive result from the F.D.A., due to the low hazard to patients, the fact the device is not implanted and therefore does not come into contact with internal tissue, and it does not make diagnostic decisions on behalf of clinicians.

The present status of F.D.A. approval does not pose significant obstacles to current marketing activities, which focus on investigational users and distribution partners.

***Progress in Development of the Flexible Probe***

Devices for applications in gastroenterology have been the secondary area of major development focus during the period. Strong progress has been achieved in the miniaturisation of components for prototype flexible or rigid probes for microscopic examination of body cavities, such as the colon.

Potential applications in gastroenterology include:

- Colon cancer
- Mouth cancer
- Gastric cancer
- Barret's oesophagus
- Ulcerative colitis
- Cancer management

In parallel with the probe development, animal studies have been conducted to investigate several of these applications. With the use of human-safe contrast agents, results of these investigations have been very encouraging. We now consider that certain of the protocols tested will be suitable for clinical trials. As a result of recent progress in development of appropriate clinical grade prototypes, we expect to commence clinical trials in gastroenterology in the very near future.

This report has been made in accordance with a resolution of directors.

Peter Delaney  
Managing Director  
Melbourne  
15 March, 2001