Optiscan Annual General Meeting

CEO Address

The 2003/04 year has been one of significant and solid progress on Optiscan's path to becoming a successful medical devices business.

We have worked hard to develop our business in accordance with our strategic plan of April 2003. We have achieved significant progress against that plan.

To provide a description of that progress and to accurately review the past year, four key topics need to be presented.

I will commence by talking to you on two of these, technology transfer and regulatory clearances before handing over to our Director of Technology, Peter Delaney, to talk about probably our most important advances which are in the area of, clinical trials and establishing medical efficacy. Peter will then hand back to me to talk about the fourth, partnership formation.

I will then conclude with an explanation of the path forward with Pentax for the flexible endo-microscope and a brief review of our financial position.

Progress On Key Milestones

But first I want to review progress made against the key strategic milestones as presented at last year's AGM.

These seven strategic milestones were identified as key for our business to unlock the value of its technology and secure commercial success.

During the year two more were completed, bringing the total to four key milestones achieved. As you will hear significant progress has also been made on the three remaining milestones.

We set ourselves aggressive timelines for completion of these milestones and while progress has not been as fast as we had initially planned I and your board are very satisfied with the substantial progress we have made. We firmly believe that Optiscan is now well on the way to becoming a commercially successful business.

Technology Transfer to Create a Supply Chain

Significant efforts transferring technology and know-how from Optiscan to Pentax and to Optiscan's sub-contract manufacturers have been a feature of the year's activity.

Our technology and know-how had to be transferred to enable efficient and scalable production of the Pentax flexible endo-microscope system.

The product supply chain we have created features:

- Sub-contract manufacturing of:
  - miniaturised scanner inserts
  - confocal control box modules
- Optiscan final calibration, integration and testing
- Pentax manufacture of the scopes and completion into a finished endo-microscope system

We selected separate and appropriately skilled Australian subcontractors to manufacture the miniaturised scanner inserts and the confocal control boxes. Over the last year we have then worked very closely with each of them to transfer our technology and our extensive know-how.

This has proven to be a significant task, especially for the miniaturised scanner inserts where precision optical alignment of fibre and lens is a key requirement.

In Japan, Pentax needs to be able to assemble the insert into an endoscope and then test all the functionality of the final completed endo-microscope system. We have had to transfer comprehensive final testing capabilities to Pentax and have had to work with their people to ensure that the assembly process is completed without disruption to the alignment and the calibration of the insert.

These technology transfer processes have been characterised by detailed documentation and technical exchange between our R&D engineers and their counterparts at Pentax and our sub-contractors.

Another feature of the technology transfer programme was Pentax's extensive product testing regime, which had to be completed in Japan and included some testing outside of the original design specifications.

This resulted in the need to make minor refinements to some aspects of the design and the production procedures being used. Making these very small changes was an unforseen and time consuming process, especially given that design and production were being done here in Australian and testing was predominantly being completed in Japan.

The net result of all this technology transfer activity and rigorous product testing is a final product capable of high and consistent levels of imaging performance.

Technology transfer has been a challenging, exacting and at times difficult process. But we have succeeded in completing it and we are exceptionally pleased with resulting product.

Regulatory Clearances and Quality Accreditation

I now want to turn your attention to the second key area of activity, regulatory clearances.

The process of getting regulatory clearance for any medical device used inside the body is necessarily thorough and exhaustive. As patients, we expect no less.

The strategy adopted by Pentax to achieve regulatory clearance for our technology drew on their extensive global experience.

The CE Mark clearance regime required for medical devices in Europe features two components; audited compliance with the European Medical Device Directive (MDD) and ISO quality certification of production processes.

The first component we addressed was the quality certification. This involved Optiscan becoming an original equipment manufacturer supplier to Pentax as part of an integrated quality approved supply chain. Pentax had to make significant changes to its quality procedures and extend its quality accreditation. Optiscan and its sub-contractors had to achieve ISO 13485 quality accreditation for medical devices.

All companies had extensive audits by auditors that are Notified Bodies to the European quality system. We received the required ISO 13485 accreditation in June. One of our subcontractors had already achieved accreditation; the other one became accredited in June. Pentax received the required extension to their accreditation in July.

To demonstrate compliance with the Medical Device Directive (MDD), We worked withPentax to prepare a detailed design documentation submission covering all aspects of the design and testing processes. Pentax's German based auditors then audited both Pentax and Optiscan on this submission before they authorised compliance with the MDD.

With all these steps completed the CE Mark regulatory clearance for Europe was issued in October.

The USA's Food and Drug Administration (FDA) adopts a more outcome-oriented process to ensure a medical device is safe for patient use.

The FDA provides several different approaches for companies to demonstrate the required outcomes. Pentax US business chose to pursue an approach called a 510K submission where the safety of a new instrument is established by predication on instruments already in the market with FDA clearance.

Optiscan worked to provide Pentax of America all the necessary data to complete the 510K submission. This including providing data on other instruments that use lasers similar to the one used in our instrument.

The FDA's regulatory clearance was also received in October.

Fulfilling all requirements for these regulatory clearances has taken considerable effort and we are very pleased to have all the processes successfully completed.

I will now hand over to Peter Delaney, our Director of Technology to talk about the Pentax clinical trial program

Clinical Trials and Medical Efficacy

The clinical trial program has been a major area of activity for both Pentax and Optiscan over the past year.

The program commenced in early 2003 at the Cabrini hospital in Melbourne. Throughout the 2003/04 year Pentax have expanded that trial program so that it now spans four continents.

At all sites we have been active in engaging with the doctors and their nursing staff training them on the use of the trial instruments, assisting them with protocol design and the required ethics approvals. We have also been particularly involved with image interpretation to help the initial doctors realise the full medical significance of what they are viewing.

The results that have been obtained and published have been truly excellent. In data made public during the year, clinical investigators reported extremely high sensitivity, specificity and accuracy outcomes for detecting neoplasias (very early cancers) in two clinical studies. Overall accuracies as compared to biopsy for both groups were above 99%.

These results are absolutely stunning. They have surpassed our and Pentax's best expectations.

A testimony to the significance of these results is that they were selected for rapid communication in "Gastroenterology", which is the leading international peer-reviewed journal in the field of gastrointestinal medicine. A rapid communication means that editors consider the article so significant to their field of medicine that it should take precedence over other papers waiting for publication.

In addition, the article received enthusiastic editorial coverage, including visionary statements as to the likely impact on clinical practice.

And in a final highlight, having the entire cover dedicated to flexible endo-microscope images, has really guaranteed the highest levels of awareness amongst the target market.

I now want to play a short video clip from a procedure so that you can get a real appreciation of how the doctors use our technology in theatre.

The clip is taken from one of several; demonstration day procedures run by Pentax to introduce endo-microscopy to groups of gastroenterologists.

While this clip shows part of a clinical procedure there is no blood - only guts - and hence I do not expect you to find it at all disturbing. If you do feel queasy please close your eyes and I will let you know when the vision has finished.

You will see a blended image that shows the doctor performing the procedure in this case Dr Ralf Kiesslich and the image displays of his instruments.

This particular clips sound track is in German so I will explain the setting and a brief translation of proceedings.

These demonstrations involve live audio-visual broadcast from the procedure room to doctors in a nearby lecture theatre (sometimes several hundred), complete with two way communication between the endoscopists and the audience and the so that interactive question and answer can be conducted via a moderator in the auditorium.

Digital images captured from this process and educational material describing their interpretation can be found on-line at www.endomicroscopy.org.

I hope you found that informative and the medical procedure clip has now finished for anyone who is looking away.

The above application and its success at trial relates to screening for colorectal cancer. In addition, other applications are also producing exciting early results. We expect the program to continue to yield data supporting the use of confocal endomicroscopy for a range of procedures associated with ulcerative colitis, gastric reflux (heartburn), and bacterial infections of the stomach that cause ulcers and gastric cancer. These are all presently being investigated.

Moving forward with the Pentax trial program involves collecting standardised data from a controlled multi-centre trial. Pentax is now well advanced in planning these trials, a process in which Optiscan is actively involved.

Partnership Search

Over the last twelve months we have accelerated our activity levels greatly in the search for a second commercial partner for our miniaturised confocal technology.

The establishment of a new partnership in rigid endoscopy and/or in research laboratory microscopes remains a key objective for our business. We have invested considerable resources to miniaturise our scanners for use in endoscopes and a second partnership using the same miniaturised scanner technology will greatly improve our profitability and commercial success.

Both these markets provide potentially attractive partnership opportunities but the rigid endoscope one offers significantly greater potential, especially in the medium term.

Virtually all potential partners are based overseas in either the USA or Europe and hence our activity in finding a suitable partner has included a lot of travel. Since the last AGM we have completed no fewer than 18 overseas trips, visited 13 different companies involved in rigid endoscopes and 5 involved in laboratory research confocal. In total we have met, discussed and/or demonstrated our technology with more than 70 people from potential partners.

We announced during the year that one of the leading industry players in the research laboratory microscope market was conducting an evaluation of our technology. This evaluation confirmed the existence of a range of laboratory research applications where our miniaturised confocal scanner technology enables researchers to do new and innovative research.

However, in April both companies concluded that a mutually acceptable commercial partnership arrangement could not be negotiated. In particular the potential partner's desire for Optiscan to do additional design modifications at a time when resources were needed for the Pentax project proved to be prohibitive.

This was a disappointing outcome. It is worthy of note that the potential partner has advised that they remain interested in potentially working together at some time in the future.

In rigid endoscopy, the publication of the excellent clinical trial results obtained with the flexible endo-microscope significantly increased the interest shown by potential partners.

To further increase interest we have been active in developing an overall understanding of rigid endoscopy applications, considering key factors of:

- Strength of medical need
- Size of market
- Definition of the exact procedure to be completed by the doctor
- Procedure economics
- End user buyer behaviour
    - Location of equipment (hospital, day procedure centre or rooms)
    - Capitalisation of buying entity
- Competitor technologies or techniques

This has involved us actively talking to leading doctors and conducting background research on the economics associated with potential applications.

Leading application also utilise the key clinical benefits of our technology over traditional biopsy methods, namely being

- non-invasive
- real time
- lower cost

Leveraging these benefits and combining with the sought key market characteristics has led us to identify two high potential application areas of most interest to potential partners.

The first is diagnosis performed during a procedure. This leverages the real time diagnostic capabilities of our technology to achieve better outcomes during surgical procedures – especially during cancer surgery.

The second application area of great interest is obtaining cellular level diagnostics from tissues that are not suitable for biopsy. Most notable here are the eye and weight bearing cartilage.

Currently there are four separate companies that have completed non-disclosure agreements and are at various stages of progress in discussions and/or negotiations concerning using our technology for one or both of these applications and potential partnership formation.

While it is impossible to predict when a partnership agreement will be completed we are definitely a lot closer now to gaining this commercially important second partner than at any time over the last twelve months.

We have made truly significant progress in all of these four key areas of our business and our activities over the year have created the necessary base upon which we can commercially develop our business.

I now want to outline the immediate future looking forward with Pentax.

Moving Forward with Pentax

Pentax and Optiscan have always considered that success in market for the flexible endo-microscope will be achieved when three elements are complete.

- Regulatory clearances
- Strong market awareness
- Scalable supply of product

As outlined earlier we have worked hard to receive the important FDA and CE Mark regulatory clearances.

Strong market awareness has been created by a mixture of the flagship publication in "Gastroenterology" and by Pentax's efforts to exhibit the

instrument at leading conferences around the world and through the demonstration days they have organised.

With regulatory clearances in place Pentax can accelerate their market awareness efforts through the introduction of product specific promotional materials. In each of their geographic regions Pentax is currently preparing such material and scripted presentations that their sales force representatives can use with their customers.

Pentax sales force representatives, many of whom are paid solely on commission, are enthusiastically lifting awareness amongst their customer base. They are genuinely excited about having a unique breakthrough product that their competitors cannot offer.

With this activity ongoing, market awareness will only get stronger.

The third element of scalable production has been completed by Optiscan but must now be completed by Pentax.

As we announced in October we have already shipped product to Pentax partially fulfilling the initial order they placed on us. Pentax will use this product to finalise the engineering of their own processes before transferring them from a pre-production environment into full production.

Obviously the timeline for completion of this process of transferring to full production is solely within Pentax's control but they expect to have it complete in the first quarter of 2005. This will enable them to achieve full sales release before their new sales year commences on 1 April.

By early next year we expect to have comprehensively addressed each of these three elements.

So given this, the key question is, "How many will we sell?"

At this stage the answer is still impossible to provide.

Forecasting sales rates of new technologies is notoriously difficult to get right.

However Pentax are currently engaged in a typically thorough and methodical analysis of expected market uptake. They are doing this because they know they have to place a follow up order on us for supply of product ahead of sales release.

Therefore we think the best indication of likely short-term sales success will be the size of that follow up order.

We will be sure to announce the size and nature of Pentax's follow up order(s) when it is received.

Financial Position

A review of our company's financial results shows that we again traded at a loss last year as anticipated and advised at last year's AGM.

The loss was $3.36M and was within a few percent of our budgeted expectations.

This result reflected the ongoing expenditure incurred in R&D/engineering to complete the technology transfer and the minor design changes I described earlier.

We delivered the anticipated full year benefits of the strategy review with non-development expenditure down by 44% to $3.26M.

Revenues and margins from the initial Pentax order are now flowing but will remain modest until Pentax completes all activities for sales release and we supply follow up orders. As outlined earlier Pentax's sales release is due in the first quarter of 2005.

We expect to record a loss for this current financial year.

The one event that could cause us to report a profit for the current year is the successful conclusion of a partnership in rigid endoscopy that features significant up front payments.

We have maintained prudent management of out cash reserves. We commenced the year with just over $15M of cash and closed the year where we anticipated at just under $10M. At present we have $7.5M cash on hand.

Our current cash burn averages $0.5M per month. We expect this level to be maintained with the one off exception that we will need to commit working capital to our supply chain as Pentax production gears up over coming months.

Looking forward

Looking forward to next financial year, our earnings result is very difficult to forecast due to the uncertainty of Pentax sales and the potential upside of a rigid endoscope partnership.

If our business was looking to breakeven relying solely on revenue from sales of flexible endo-microscopes to Pentax while preserving current resourcing in order to secure a rigid partner, then we would need to be selling approximately 200 systems a year with an average of two scopes per system.

Completing sales of 200 units during the 2005/06 year is possible, but it would be at the upper end of our current expectations.

However, a successful conclusion of a rigid partnership arrangement could provide significant positive upside for our 2005/06 result.

Our outlook projections on cash indicate that if we are required to undertake a significant ramp up in working capital for Pentax and/or our funding of rigid endoscope development work enables us to secure the right partnership deal, then it may become prudent for us to undertake a modest capital raising.

As with the case of the Pentax deal, upfront payments and/or an equity component may feature in the partnership arrangement negotiated for rigid endoscopes and hence the new partner may become the source of the required cash.

Summary

In conclusion our company continues to make significant progress in its business base and is now well on the way to becoming a successful medical devices business.

With clinical efficacy of our technology established, Pentax rapidly gearing up for full sales release early next year and strong interest from potential partners in rigid endoscopy I believe that our business is in a stronger position today than at any other time in its history.

Your board, the management team and I look forward to building Optiscan into a commercially profitable and vibrant medical devices business over the coming years.

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