Optiscan Imaging Limited

AGM 2006

CEO Address

I am pleased to be able to report the significant progress that has been made developing and commercialising our company's unique endomicroscope technology.

I will combine with Peter Delaney our Director of Technology to do this in three parts

- First I will provide a review of the company's activities and achievements over the past year.
- Peter will then review the considerable progress made in clinical application development, multi centre trials and the path to reimbursement. This update is very important in understanding the key aspects of what drives sales growth and our path to profitability.
- I will then conclude by providing an update on commercialisation and comment on outlook going forward.

Pentax ISC 1000 Flexible Endomicroscope

When we look back at the 2005/06 financial year the obvious stand out achievement was Pentax's 1 March release of the ISC 1000 flexible endomicroscope system.

Sales of endomicroscope systems and miniature scanners to Pentax for the ISC 1000 has driven the strong revenue growth seen last financial year. By 30 June we had shipped 47 systems, enabling us to record product sales of $3.23M, up over 300% on the previous year.

Pleasingly for shareholders the commencement of significant sales revenues was recognised in investment markets and resulted in a re-rating of our share price.

As expected Pentax sales and market development activity also accelerated with the market release of the endomicroscope. This included a special symposium at this year's DDW and numerous live procedures being performed at major, national meetings of Gastroenterologists in a number of countries around the world.

This has been an exciting culmination to a substantial effort over many years to design, test and transfer to full scale manufacturing our endomicroscope technology.

Optiscan FIVE 1 Pre-clinical Endomicroscope

During the last year the design and development activity to create a second commercial business stream for our company was undertaken. Following some strong initial feedback from users of prototype rigid endomicroscopes we created the Optiscan FIVE 1 endo-microscope for pre-clinical research use. FIVE Stands for Flexible In Vivo Endomicroscope and 1 because the instruments extreme simplicity of use.

The target markets for the Optiscan FIVE 1 are pre-clinical drug development research and doctors w utilising preclinical research to assist them in their clinical research endeavours.

The unique ability of the Optiscan FIVE 1 to provide real time imaging of cellular level events free from the significant disruption to any research created through the surgical removal of the tissue is of great interest to both target market groups.

The design and development expenditure incurred was modest and strongly leveraged the production base created from supply to Pentax of ISC 1000's.

During the year the FIVE 1 progressed from concept to final production ready for initial sales. I will elaborate further on the current status of FIVE 1 a little later in the presentation.

Other Achievements

Other achievements during the year were

- Further outstanding clinical trial results for flexible endo-microscopy
- Successful pilot clinical trials with rigid endo-microscopes
- A significant upgrade in regulatory certification enabling us to self certify for CE Mark
- Establishment of volume production facility

Also reported recently was the successful conclusion of negotiations that were ongoing for most of last year on back royalties relating to 2004 patent territory extensions granted for Europe and Japan on our core patents. Total settlements of $2.6M were negotiated with $2.1M to be recorded in this half year.

During the year our resources progressively freed up from near 100% involvement with Pentax. This enables us to move forward with development of other future business streams and significantly strengthen our product pipeline.

Key projects include:

- Rigid endomicroscopes – featuring completion of pilot clinical trial activity with prototype designed and manufactured instruments
- Second generation endomicroscope platform is a major undertaking and includes a comprehensive rewrite of system software and development of innovative new smaller scanners
- Bronchoscope development for use study of lung diseases
- Multiphoton endomicroscopes for deeper tissue imaging. This is being partially funded by a A$1.9M Federal Government Commercial Ready Grant

Ongoing research and product development remained our largest expense area and your board believes that this effort will unlock further commercial potential from our technology.

Our resulting financial outcomes were very much improved on the previous year's performance.

- Our operating loss was $3.8M down 26% from the previous year's $5.1M
- This was achieved from the profit margin on our product sales, reductions in expenses and increased royalty income
- Our cash usage was $5.1m, of which one third was invested in working capital to support our production activity. Our "non working capital" cash usage reduced 29% to $3.4M

I will now hand over to Peter to update you on the significant progress with clinical efficacy studies and to outline the process we are following to gain additional reimbursement for use of our endomicroscopes.

Address by Peter Delaney, Director of Technology

It is my pleasure to provide this update on progress in clinical trials and market development for endomicroscopy in several application areas.

This year has seen tremendous progress in the profile of endomicroscopy, in terms of published trial data, profile in the endoscopy community, training of endoscopists in the technique, and the sales release of the flexible endomicroscope by Pentax

Endomicroscopy studies have continued to deliver exceptional efficacy data in growing number of applications. I will not go through these in detail, but you can see from this slide that the sensitivity, specificity and accuracy data reported so far for the ability to predict pathology results using endomicroscopy is at a very high level, which is in fact comparable for most of

these applications to the numbers obtained if comparing different pathologists opinions on the same biopsies.

The number of applications in which flexible endomicroscopy has delivered excellent efficacy data has expanded. Around this time last year, compelling supporting data was available for 5 separate applications. This has increased significantly, with 9 separate applications now reported by investigators and associated with impressive efficacy data.

In addition to this progress in flexible, 2 applications for rigid endomicroscopes were investigated in pilot clinical trials during the period, yielding promising preliminary data worthy of further clinical investigation.

The bibliography of published works has also grown substantially. Last year, we reported success in achieving a high profile original research paper in *Gastroenterology*, the higest impact publication in for gastrointestinal endoscopists. Since that time, the bibliography of published studies in endomicroscopy has grown significantly and now features 11 original articles, 8 reviews and more than 30 conference abstracts and presentations. Furthermore, the original *Gastroenterology* paper published in September 2004 has since been cited in 40 other publications, demonstrating the ongoing impact of this work.

In addition to this profile in the peer reviewed clinical scientific literature, live demonstrations served as a key educational tool. The number of live demonstrations has increased from 3 in calendar 2005 to 9 in 2006, all broadcast to organised events in gastroenterology, some being major congresses, and some being specifically organized to showcase endomicroscopy alone. It is now becoming routine for endomicroscopy to be included amongst live cases used to teach endoscopic techniques at major conferences and medical education events. This is a powerful promotional tool as it shows the ease with which endomicroscopy can be performed and the consistency with which microscopic images can be obtained. Attendees often comment that the utility becomes obvious during these demonstrations, and they gain confidence in the reliability and ease of the technique.

And of course, beyond demonstrations, the growth in uptake in endomicroscopy will depend on the access to training. The University of Mainz in Germany is the first major training centre, primarily for European doctors but also for US and Asian visitors to the centre. Attendees see multiple procedures first hand, receive detailed theoretical tuition in image recognition, and ultimately perform “hands-on” procedures. Doctors interested in purchasing endomicroscopy often attend such training ahead of installation at their own institution. During calendar 2005, 16 doctors were trained in Mainz, and this has risen sharply to nearly 50 trainees so far for calendar 2006. This is a key centre for propagating the foundation knowledge from clinical studies into reliable and reproducible clinical practice.

In addition, Johns Hopkins Hospital, the number one ranked US hospital, is now established as a key US reference centre and is actively involved in the

establishment of standards of learning and performing endomicroscopy in the US environment.

Importantly, both of these key sites have undertaken a formal transatlantic collaboration that was announced in July this year. This involves active basic research, best practice and teaching of endomicroscopy as one of the lead areas ocollaboration.

The growth in the number of applications, availability of training, and increasing profile of endomicroscopy is reflected in a trend towards greater utilisation by new users. While many of the original users of endomicroscopy would have typically used it in one or two main applications, at rates of one to two procedures per week, recently established centres are typically performing in excess of 20 procedures per month. At least one hospital (in the UK) has purchased multiple systems with intent to setup more. This trend towards mainstream workflow reflects an important shift in the acceptance levels of endomicroscopy towards widespread adoption.

Slide 6 is the world map of endomicroscopy sites as at this time last year. This preceeded the sales release by Pentax in March 2006, so it naturally represents the network of trial sites established by Pentax at that time…

Since that time, and spurred especially by Pentax's sales release, this has changed substantially with leading hospitals in a growing number of countries purchasing the system. As well as additional hospitals in USA, Germany and Singapore systems are now in use in hospitals in China, Thailand, Israel, South Africa and the UK.

As mentioned, training centres are also being established, the first two of which are shown here in Mainz, Germany, and at Johns Hopkins, USA.

You can see from this picture that the US market has been slower to develop than the European market, due in part to the lack of established reference or training centres over the past two to three years.

However, the profile of endomicroscopy at US based conferences and events has grown steadily, and the establishment of the technology in Johns Hopkins Hospital is associated with a significant shift towards uptake by a prestigious list of US hospitals soon to be installed. Importantly, the strong ties between Mainz and Johns Hopkins offer a key mechanism by which development of training infrastructure in the US will leverage the progress and experience base in Europe.

So, where does this excellent progress place endomicroscopy on the path to ultimate success and acceptance into mainstream endoscopy?
To properly answer this question, we need to first understand that market development requires a co-ordinated prooression of scientific and commercial activities.

Firstly, all marketing activities for medical devices must be built upon a strong foundation of clinical science, and the quality of data supporting the benefits of the technology is critical.
The development of the clinical science requires the following steps.

First, market research identifies potential applications and quantifies those that represent substantial medical need and market potential.
Those applications that represent worthwhile markets for endomicroscopy are typically first investigated in pilot trials. These do not necessarily establish the overall effectiveness of the technique but allow the feasibility to be established.

Once applications appear feasible, the efficacy can then be established in single centre studies by opinion leading investigators. These can measure the extent to which the technique works and produce data for scrutiny by peers and the scientific community.

If the technique appears to be useful based on these study outcomes, then larger, more rigorously conducted multi-centre studies are required in order to measure how reproducible the technique is in the hands of multiple investigators in multiple environments. Positive outcomes of such trials provide influential data supporting the adoption of the technology.

Signposted by key achievements in establishing this scientific foundation, the following commercial activities can be developed.

Firstly, awareness can be built even when very little clinical data has been produced. This stimulates interest in the technology and invites further input from the medical community as to the future directions for advancing.
As outcomes start to emerge from single centre studies, successful awareness building can create significant demand for purchase of instruments. Such sales are typically to teaching hospitals and early adopters, which represent a subset of the ultimate market. However, outcomes of studies at this stage do not allow additional marketing claims (such as diagnostic claims) to be attached to the system, and so the demand is based purely on profile and demonstrated efficacy from single centre studies.
However, successful outcomes from multi-centre studies, if conducted properly and producing positive results, can support the registration of efficacy claims (such as diagnostic efficacy in a specific patient group). This can provide the sales force with the ability to promote tangible benefits to using the technology and would be expected to boost sales significantly.

While the market is growing as outlined above, purchasers of the system also accumulate experience and can provide additional data on the utility of the technology outside the context of formal trials (thus generating so called 'community data'). Ultimate success requires that doctors using endomicroscopy receive additional reimbursement, providing financial coverage and incentive to utilise endomicroscopy. There is no single event, trial outcome, or regulatory approval that leads to reimbursement, as health care payers must be convinced of the overall cost-effectiveness of the technology. This is typically sought by lobbying the insurers armed with

appropriate data from multi-centre studies, registered marketing claims, and broader based community data supporting the health-economic rationale for paying for the use of the technology.

The extent to which gaining reimbursement drives sales naturally depends upon the quantum offered (ie the amount one can charge for performing a particular procedure utilizing endomicroscopy)..

So, using this as a road map, we can review progress for the establishment of endomicroscopy in its various applications.

The four applications listed here (detection of colon cancer in long standing ulcerative colitis sufferers, Barrett's esophagus, diagnosis of colorectal neoplasia during screening colonoscopy and diagnosis of early gastric cancer) have all been investigated for some time and are now at a stage of scientific maturity suitable for entry into multicentre clinical trials. Interest in these applications also underpins many of the sales to date.

In the area of multi-centre trials and generation of data in support of the case for reimbursement, Pentax have taken longer than initially anticipated to define and complete trial activity. Several factors have influenced these timelines, including the different applications emphasis and experience level between USA and Europe (Europe being more advanced in the pursuit of endomicroscopy). This has led to redefinition of trial strategy, with plans for several separate regional multi-centre studies spanning several applications.

At this stage, the details of Pentax plans remain confidential, however In compliance with World Health Organisation guidelines for conduct of clinical trials, the details of patient numbers and outcomes to be measured in each trial will be registered with an appropriate organisation before commencement of clinical activity. This information will then become available.

However, with growing understanding of the technology and the interpretation of endomicroscopic images, a newer family of applications has emerged, some of which represent significantly larger patient groups than the foundation applications described on the previous slide.

Although these applications are less mature, preliminary data is promising and they are of growing interest, already forming the basis of some purchases of the system. However, further studies are required to bring the understanding of these applications and workflows to a state of maturity suitable for multicentre studies.

Considering the scientifically advanced application just listed, as well as the more recent applications above, endomicroscopy applications now span most of the major gastrointestinal disorders associated with endoscopic examination.

During the year two pilot clinical trials were initiated in potential applications of the rigid endomicroscope. Following significant technical development to enable use of a sterile sheath suitable for use in the operating theatre

environment, trials were initiated in Bankstown Hospital in Sydney, Australia, and Mainz University Hospital, Germany. Additional pilot studies are planned in the US with timing subject to final site selection and investigator IRB progress.

The Bankstown trial features investigation of surgical resection margins during pancreatic cancer resection surgery (the Whipple procedure) in tissues of the pancreas, bile duct and surrounding organs. The Mainz trial features laparoscopic (keyhole) examination of liver disease in patients with suspicion of liver disease including fibrosis, fatty liver disease and cirrhosis.

Both studies have yielded important feedback leading to some instrument modification, and resulted in successful validation of the overall ergonomics and usability of the probe. The studies have validated that surgeons can easily obtain stable images and control the system in the context of the relevant surgical workflows.

The trials have so far accrued nearly 20 patients each. On reaching target patient numbers of between 20 and 30 patients per trial, analysis of the images obtained will be conducted including comparison with conventional histology of the tissues that was imaged by endomicroscopy. Based on this analysis, further trials are expected to be planned aimed at obtaining efficacy data in one or more of the applications.

In addition, an additional pilot trial for laparoscopic (keyhole) examination of abdominal organs in women suffering the condition endometriosis is being planned.

A substantial list of other possible applications remains the subject of ongoing market research for consideration as possible subjects for clinical studies in the future.

The technical achievement to move the rigid probe into clinical studies is a significant one and now the selection of applications for pursuit in more extensive studies will depend on the performance of the technology in the pilot trials.

So, in summary, our technologies are now used in three main categories of clinical applications at different stages of maturity

Firstly, the advanced clinical applications for the Pentax flexible endomicroscope have already yielded compelling efficacy data in numerous single centre studies,. Some of these applications are heading for multi-centre studies with potential to support the attachment of diagnostic efficacy marketing claims to the product in the foreseeable future.

Secondly, there is a family of applications that are potentially more mainstream than the first group but which are less mature. These applications have preliminary clinical data showing promising efficacy, and these applications are perpetuating interest among opinion leaders, as well as driving sales to key investigator groups.

Finally, beyond flexible endomicroscopy, we now have preliminary clinical data in pilot trials of the rigid endomicroscope and expect to choose lead applications for expanded studies soon.

We believe endomicroscopy has now pervaded the mindset of multiple medical disciplines, is supported by exceptional scientific evidence, and is now well placed to continue into the mainstream, first and foremost in the growing field of gastrointestinal endoscopy

Thank you for your attention during this update and I will now hand you back to Matthew Barnett.

CEO Address

I now want to outline the current state of progress in our business commercialisation and provide an outlook for the future. I will first comment qualitatively on the key business areas and will then address what that means in terms of system sales and financial performance.

Flexible Endomicroscope Outlook

As Peter explained during his address, endomicroscopy is proving itself to be an incredibly powerful imaging modality with huge market potential. It is therefore not surprising that Pentax are now actively positioning endomicroscopy as their flagship new technology product line.

The progress they have made to date with marketing and sales of our technology is overall best summarised as "solid". It must be said, however, that there are aspects where we hoped more would have been achieved.

We have been very pleased with sales activity and outcomes in Europe, SE Asia and Australia where focussed sales based activity commenced well before product release in March this year. This success has been built in part on the training capabilities that have been created during the clinical trial program, especially at Mainz University in Germany.

In North America focussed sales activity really only commenced this year after product release and DDW in May. Since then the US have been very active in building a strong order book with many prestigious and high profile hospitals keen to utilise the technology. However to date, a lack of training infrastructure and experienced doctors have significantly retarded the number of the systems sold.

In this context we were particularly pleased that Johns Hopkins Hospital is establishing itself as a centre of excellence for endomicroscopy with a strong training emphasis and is undertaking active collaboration with the Mainz

Hospital. We believe this will be an important step in accelerating USA sales growth over coming quarters.

Obviously our business relationship with Pentax affords us very little direct control of sales and market development. The terms of our agreement provide that they have responsibility for these activities, including clinical trials and achieving reimbursement. As we move forward with the commercialisation of our technology, progressing from development to product in market, the relationship between our companies is evolving and changing. The interaction and collaboration on design and engineering issues that characterised the early stage of our relationship is now less in evidence.

We do not have the same visibility of their manufacturing, service and regional sales organisations, and there are fewer formal channels of communication. While at times this is frustrating, we actively look to contribute to these activities wherever we believe we can assist, and our input is highly respected in most parts of the Pentax organisation.

In relation to sales forecasts this reduced visibility of sales and marketing activities is particularly apparent, and I might say, particularly frustrating.

We are well aware that everyone wants to know where our sales are heading, but I have to say that this is a particularly difficult question at the moment.

Pentax have placed very solid orders on us over recent months, and as we will discuss shortly, we expect to be a little behind schedule in meeting their requirements through to December. However, into the early months of 2007, Pentax current forecasts are soft, suggesting lesser demand than we believe is present.

We find this difficult to interpret, given our direct observations in market of robust sales demand and Pentax's plans to accelerate trial activity in the USA and Europe.

Although a lumpy start to sales of a new technology is not uncommon, we have some concerns, largely emanating from this lack of visibility, and we are actively pursuing the matter with Pentax at present to try to obtain a more fulsome view of forward sales and product requirements.

Our confidence in our technology has never been higher. The outstanding clinical trial results and the associated disease incidence and prevalence data make the Board increasingly confident that endomicroscopy will achieve appropriate reimbursement and grow to capture at least a 10% share of all flexible endoscope systems sold.

Optiscan FIVE 1 Outlook

We are hopeful that the December quarter will see the first sales of Optiscan FIVE 1 instruments.

Securing initial sales has taken longer than expected due to unforeseen requirements and time to complete the necessary paperwork for component flammability and laser safety. All regulatory clearances for CE mark have been completed, but USA filing requirements, whilst very close, are not yet complete.

At present two systems are being trialled by prospective customers and we have quotes out on a further 9 instruments.

Last month we exhibited the Optiscan FIVE 1 at the large Neurosciences congress in the USA. This is premier annual congress for research microscope manufacturers to exhibit new products and instrument capabilities. The instrument drew a positive response from congress attendees with the result that several potential customers have requested follow up and quotation.

Overall we are very pleased with this level of sales interest and activity. It is consistent with our initial sales target of 10-12 instruments per year.

Rigid Endomicroscope Outlook

Rigid endomicroscopes will be the second medical market product line for Optiscan.

As Peter described earlier we have been progressing pilot clinical trials in selected high potential rigid applications. The primary purpose in completing these pilot trials is to increase the value demonstrable in our technology for specific market opportunities.

Since August when we reported progress in these trials against two of our three key end points further potential partners have expressed interest in collaboration for specific applications and have commenced dialogue with us under confidentiality agreement. There is now active dialogue with 6 potential partners for rigid endomicroscope applications.

We are very confident that our endomicroscope technology will demonstrate high levels of efficacy in rigid endoscope markets, especially in providing doctors with real time information to assist them make surgical decisions during surgery procedures.

Accordingly we are determined to consummate appropriate partnership opportunities for rigid endomicroscopes. Discussions and trials are advanced to the point where a deal could be completed quickly. However, any partnership must secure appropriate value for Optiscan through controllable development of attractive market opportunities. We are in no hurry to do the wrong deal.

Our trial program will continue to build demonstrable value in our technology while our discussions with potential partners continue.

Expansion of Manufacturing

With the commencement of meaningful production volumes of Pentax product and with further future growth expected in coming year(s) we decided to expand our scanner production space and simultaneously upgrade the infrastructure to obtain clean room ISO 8 standard.

For a relatively modest investment we have improved the production environment significantly ensuring we can reliably build high quality current and future scanner designs.

These building works created some disruption to production throughput over recent months. While the works were planned to coincide with the quieter sales period associated with the Northern Hemisphere summer it still had an impact on our production throughput.

These building works have recently been completed and we are very proud of our new facility.

Financial outlook

Firstly I advise that we expect product sales in the current half-year to December to be similar to the $2.6M recorded for the six months to end June with an anticipated 45 -50 systems sold.

These sales levels were impacted by production time lost during the expansion of manufacturing facilities and as a result we expect to be slightly behind on Pentax orders at the end of December. We expect this shortfall to be filled by the end of January.

With the addition of the $2.1M in back royalty settlements to brought to account during the half year we expect our net profit result for the first half of the financial year to be a small loss, perhaps near breakeven.

As set out during last year's AGM we need to sell about 200 systems per year to support the entire company including ongoing research and product development. The effect of the back royalty payments has been to reduce the number of systems needed to become profitable this year down to approximately 120.

However, as I discussed earlier, the outlook for sales in the second half is somewhat uncertain at present, and until such times as we get to the bottom of the Pentax forecasts, it remains to be seen whether we will reach that breakeven level of sales.

As stated earlier the board is increasingly confident that endomicroscopy will achieve appropriate reimbursement and grow to capture at least 10% of the flexible endoscope market. This will take some time to achieve but equates to sales rates of well over 500 systems per year.

Summary

So in summary it has been an outstanding year for our company and one in which we achieved our first significant revenues, but it was not without its challenges.

Clinically our endomicroscope technology is establishing itself as a significant new imaging modality in flexible endoscopy clinical practice with early sales achieved and significant sales potential established.

We continued to build value into our unique endomicroscopy technology platform through the introduction of the Optiscan FIVE 1 and pursuit of rigid endomicroscope applications and partners.

Matthew Barnett
8 November 2006