



## **ANNUAL GENERAL MEETING 2007**

### **Chairman's AGM Address 2007 Grant Latta**

Good Afternoon,

Welcome to the 2007 Annual General Meeting of the members of Optiscan Imaging Limited.

My name is Grant Latta, and I am Chairman of the board of Optiscan.

I would like to introduce my fellow directors present today

From my left they are

- Mr Matthew Barnett, the Managing Director
- Mr Peter Delaney, the Director of Technology
- Mr Keith Daniel
- Mr Tony Rogers

I would also like to introduce the management group.

In addition to Matthew Barnett and Peter Delaney, the other members are:

- Mr Bruce Andrew, who is Company Secretary and CFO
- Dr John Allen, IP and Commercialisation manager, and
- Dr Robert Pattie, the R&D Manager.

I now formally declare the meeting open, as there is clearly a quorum present.

The course of business today will cover some brief introductory remarks, and I will then move on to outline

Our future plans,  
The business opportunities we will pursue, and  
The business model we will adopt moving forward.

I will then hand over to Matthew to provide a detailed review of operations.

As I expect you are all aware, Matthew has tendered his resignation and will be moving on at the end of the year.

I will comment further on this matter, and our progress with engaging a new CEO a little later in proceedings.

After Matthew's address, Peter Delaney will provide a comprehensive update on our technology and the future directions and opportunities that are emerging.

We will then deal with the statutory items of business, being the resolutions included in the Notice of Meeting.



When those formalities have been completed, I will open the meeting for a question and answer session, where you will have the opportunity to raise any questions that are not dealt with in the presentations or during consideration of the formal resolutions.

Mr Don Brumley, from our auditors, Ernst & Young is available to respond to any questions you may have concerning the conduct of the audit and the preparation and content of the auditor's report.

Before we move to the presentations, I would like to take a moment to thank our staff for their contribution over the past year.

They are and remain true believers in our mission.

They recognise the potential of our technology, and they understand the rigours, risks and challenges of the biotech industry.

There are probably easier jobs elsewhere, but our staff are very committed to seeing our technology succeed in the global market.

I would also like to express my thanks to Keith Daniel and Tony Rogers, the two non –executive directors, who have continued to provide invaluable assistance and wise counsel over the past 12 months.

They are selfless with their time and commitment to the company, and I thank them for their ongoing support and contribution.

I now want to turn to the path forward for the company.

## **CEO**

In relation to the CEO role, I can report that we are at an advanced stage in the recruitment process, and we are currently assessing a short list of potential candidates.

Your board has been extremely thorough and diligent, as this is an important role, at a very important time for our business.

We will, of course, advise you as soon as the matter is concluded and an appointment is made, which we expect will be in the very near future.

## **New Business models**

As we review our strategy for the future, we are critically aware of our reliance on Pentax in the flexible endoscope market.

It is a function of an industry that is dominated by the 3 Japanese endoscope companies, Olympus, Fuji and Pentax.



It was always clear that we would have to team up with one of them, and that it would have to be an exclusive licence.

Interestingly however, when we look at the rigid endoscope market, there are important structural differences.

Here there are many players, some specialising in certain fields, and others in different countries or geographic regions.

For example, companies such as Stryker are strong in orthopaedics, but have little presence in other fields such as women's health or ENT.

Similarly, Storz is a major player in the European market, but has little presence in USA.

This fragmented market structure provides more opportunity for Optiscan, and importantly, it reduces the need to exclusively licence a particular field or application, so our single point dependence is reduced.

This market structure also provides the possibility of greater presence in the supply chain, and the potential to introduce proprietary or own brand products.

In the flexible endoscope market, we had to team up with a company that both manufactured and distributed flexible endoscopes; otherwise we would have had to go into business making flexible endoscopes ourselves.

By contrast, a rigid endoscope is essentially just a surgical fixed tube with a handle on the end. We can manufacture such a device, and incorporate our scanner to provide a final product, without the need to integrate into a partner's product or technology.

What we don't have is an international distribution and sales network, so we would need to work with others through this stage of the supply chain, but that it is very common, and there are many distributors of medical devices with whom we could work with to take our product to market.

The key driver for moving toward these business models is to retain greater control and to capture more margin, and thus, wealth and reward for our shareholders.

We believe that it is the right time for the company to embark on these new directions.

It was appropriate to partner with Pentax in 2002. Our technology had to be taken from prototype to product, a path to market through established selling channels was required, and the structure of the industry always required us to team up with someone.

Many of these challenges are now behind us, and we have learned a great deal along the way.

Our technology is on the global stage, and is recognised by regulatory authorities as well as our target markets, the hospitals and doctors.



We believe it is now appropriate for us to move forward with a more mature business model that will capture a greater return for our stakeholders.

### **New Business Developments**

I am pleased to report that we are now embarking on a major new initiative in the rigid endoscope sector to provide several endomicroscopy applications in some key fields of women's health.

These applications have been identified as exhibiting the critical characteristic of a strong but unmet medical need.

Specifically, we will be targeting applications in endometriosis, cervical and ovarian cancer.

Peter Delaney will outline our plans in a little more detail in his address.

### **Business Outlook**

There are some exciting opportunities to pursue over the coming year.

In addition to our initiatives in women's health, we will also continue our collaboration with Carl Zeiss, and we look forward to releasing more information about these activities over time.

In the interim, it is important that appropriate confidentiality be preserved to optimise their commercial position.

However, I can report that we are considering an earlier release to market than was originally scheduled in our project plan.

In relation to the FIVE1 research instrument, we are receiving good levels of interest and have recently added more resources to assist in marketing this product.

These are very promising developments.

There are however, some very real challenges in our relationship with Pentax at the present time.

The Hoya acquisition of Pentax, first announced in December last year, is still playing out, and as recently as last week, Hoya announced that they have now decided to move ahead with the full integration of management.

Although this may prolong the key personnel and management changes we have experienced throughout this year, we expect it will be the last, and a period of stability should finally prevail.



There is no doubt that this takeover process has caused considerable distraction to senior management and the regional product management of confocal endoscopes.

At the end of the day however, we are optimistic about the long term effects of the Hoya acquisition of Pentax.

There is a strong alignment between Hoya's strategic goals and the technology we deliver.

We just need to get through this initial transition stage.

We reported a few months ago that Pentax forecasts were indicating a softening of sales and orders.

We have vigorously pursued this with Pentax, and have pressed for greater visibility into their internal processes.

I regret to say we are very disappointed at what has been revealed.

Pentax for the first time have provided details of sales and inventory, and it is now apparent that on current form, they are likely to order substantially less systems this financial year.

Pentax are pursuing a strategy of selling to research & teaching hospitals with our first generation product the ISC1000 and appear to be focusing their resources and major efforts on the second generation product scheduled for release in 2009 or 2010.

We have scheduled a further meeting with the CEO and President of Pentax, and I will be travelling to Japan next week.

We will be insisting that Pentax revisit their strategies for sales, marketing and service, and provide a clear plan to reinvigorate product roll out and get back on track.

We will be advising Pentax that their current performance falls well short of that expected under the terms of our agreements, and in the absence of a marked improvement, we will have to take appropriate advice and reconsider our position going forward.

We are hopeful that the distraction of the merger will dissipate, and that Pentax will redouble their efforts to get back on track.

### **Financial Outlook**

Even if Pentax responds to our urging, and restores its strategies and targets, the die is now largely cast for our current year sales.

They will be very modest, probably at the lower end of the \$1 to 2 million range.



As a consequence, we will report a loss at both the half year and full year.

Our present cash position is sound, but moving forward it will be subject to the Pentax sales position, as well as the funding requirements associated with the women's health initiative.

Accordingly, the board will carefully consider its cost structures and the possibility of further fundraising as these two issues unfold.

## **Close**

Moving forward, clearly we need to resolve the Pentax situation.

This is our first priority.

We also believe it is the right time to introduce more independence in our approach to product development.

This in turn will require us to rebalance our skill structures, with more product management and marketing experience.

In a related process, we will also review the structure of the board and appropriate succession arrangements.

We remain confident about the potential of our technology and the prospects for our company.

I will now hand over to Matthew to provide a review of our activities over the past year.



## **CEO AGM Address 2007**

### **Matthew Barnett**

It is my pleasure to again address you about Optiscan's progress and achievements over the past 12 months.

As Grant has already explained this will be my last address as CEO, so I will also take the opportunity to review the course our company has chartered over the past 5 years

But first, let's focus on the year under review.

2007 witnessed a number of very significant achievements for Optiscan. We have truly entered the commercial stage of our evolution. This was our first full year of trading with the Pentax ISC 1000 instrument, and we achieved record sales and profits from product supply.

The highlights of the year were

- Record sales of \$5.7M, up 77% on pcp
- Gross profit of \$1.8M, up 126% on pcp
- Net loss reduced by 46% to \$2.14M
- Profit from the product sales segment of the business \$1.1M, up 390% on pcp
- \$20M milestone based partnership deal with the Carl Zeiss Group for rigid endo-microscopes in one market segment
- \$7M further agreement with Pentax to achieve reimbursement for endo-microscopy and fund further instrument development
- Sales of our first "own brand" product, the Optiscan FIVE1
- Settlement of patent infringements for \$2.1M

Total revenue from all sources including royalties and grants was \$9.44 million up 68% on last year's total of \$5.63 million.

All design & development costs of a net \$3.1 million were expensed.

Cash at bank at end June 2007 was \$5.9 million. Cash consumed in operations was \$2.4 million, less than half the previous year.

A share purchase plan raised \$1.6 million, reducing the overall net cash usage for the year to \$0.8 million.

### **Pentax activity**

Our main focus during the year was the Pentax business. Following product release in March 2006, we were keen to see Pentax make a strong push into the global market. Our support for this process required engagement across a range of activities within the business.

Our applications staff were actively involved with many of the clinical trial programs including providing detailed assistance in preparation for the planned multi-centre trials.



Having completed the upgrade in our manufacturing facilities and clean room, production was busy meeting delivery schedules throughout the year. By year end we had fulfilled all Pentax requirements for systems and had no finished goods inventory.

Our service people, as well as providing direct assistance setting up new sites, had the difficult task of supporting the development and rollout of the Pentax confocal service infrastructure. This rate of rollout has remained stubbornly slow generating a corollary impact on Pentax sales businesses. By not having the necessary basic tools, training and procedures they have found it difficult to respond to the inevitable service requirements that a new technology introduction creates.

Our R&D engineers had much reduced activity levels but were still called on to provide technical support and advice, especially to Pentax engineering and production staff.

Working in this manner our sales to Pentax increased substantially. We sold 88 ISC 1000 control box systems and 95 miniaturised scanners for Pentax to build into scopes. This we well up on the 2005/06 result of 46 systems

### **New Agreement on Trials and Product Development**

During the year we also sought to reach a formal agreement with Pentax covering obtaining reimbursement for endo-microscope procedures and development of further products. In June we signed a \$7M agreement setting out that they will invest the necessary resources to achieve reimbursement and will provide partial funding of Optiscan's R&D and engineering costs to develop further endo-microscope instruments.

Pentax committing to make these investments was as a strong demonstration of their continued commitment to endo-microscopy.

Reimbursement will be achieved by completing multi-centre trials to obtain the necessary data on which Pentax can demonstrate efficacy and cost effectiveness of our technology. This data will then be used to advocate the necessary coding and reimbursement for various countries' healthcare systems. This is an involved process and we are pleased senior Pentax management have committed to complete it.

Unfortunately and somewhat paradoxically given this new agreement, the already initiated process of commencing multi centre trials again experienced delays. While we're not exactly in awe of Pentax's progress here, we recognise that it's not a straight forward process. Enthusiasm and active engagement from doctors and hospitals is often juxtaposed by requirement to get protocols and paperwork through hospital administration processes.

We realise our shareholders are sometimes frustrated at our lack of control over timelines with this important trial activity, but as is the case with any marketing partner we are not in the driver's seat of the process.

The current outlook is that the European trials will be underway this month and we are excited by this. However US trials are now behind expected and planned timelines. It is therefore likely that Europe will have results early in 2008 but the USA will be at least 6 months behind – probably more.





## **Sales Outlook**

Turning to sales progress, the outlook for our sales to Pentax in the current half year is significantly below the previous corresponding half year.

As Grant indicated earlier, we were more than a little surprised when we learned from Pentax in early August that they had accumulated excess inventory of ISC 1000 control boxes. Pressing them for greater visibility of sales made it clear to us that their US and to a lesser extent their Asian marketing activity has not resulted in reaching expected sales levels. While Pentax sales activity in all areas continues sales being made are reducing Pentax's excess inventory of control boxes and are not resulting in fresh orders on Optiscan. By contrast we are still making and supplying miniaturised scanners to be built into scopes.

Given that we are now in November, sales prospects to Pentax through to June are now very modest. It would appear on current estimates that for the current financial year we will have minimal sales of ISC systems, and a reduced volume of scanner sales.

As Grant indicated earlier, this is a matter of great concern to the board, and both the performance of Pentax and the future directions of our commercial relationship with them are now under critical review.

## **Hoya**

There is no doubt in our minds that the acquisition of Pentax by Hoya has had a significant impact on progress this year. The distraction impact on senior management has been significant and has already resulted in many senior management and Board changes including 3 Presidents in the last 12 months. The trickle down destabilising effect of these changes on all staff cannot be underestimated. Under these circumstances, we are not entirely surprised at the slower sales progress.

Such unforeseen corporate level change brings potential up side and down side risk. Pentax are aware that endo-microscopes fit Hoya's preferred strategic model of technical product differentiation and hence the product line is an attractive strategic asset. However in the short term Hoya might dismiss the current slow progress in endo-microscope sales as a minor issue in a small product line, not worthy of intervention at a time when the demands of post merger integration produce much bigger issues to be managed. With the takeover still in process and a new structure to be implemented in March 2008 we are still uncertain what influence Hoya will bring.

We are continuing to maintain pressure on Pentax to fulfil their commitments on sales, and have scheduled an important meeting for next week in Tokyo. We expect it will have a major bearing on our relationship moving forward.

## **FIVE1**

On a more positive note, last year we recorded our first sales of the Optiscan FIVE1 pre-clinical research instrument. There are now 12 units in the field, comprising both sales and demonstration systems, in Asia, Europe and USA. Researchers are using Optiscan FIVE 1s in a variety of pre-clinical investigations and research studies ranging from biomarker development through to refinement of surgical procedures.



Our focussed marketing activity is targeting key industry events and conventions. These activities and researchers publishing results and papers will build awareness and demand in the target market. We now have an extensive potential customer list and we have many active quotations for systems currently undergoing evaluation for funding.

We are increasingly confident about the sales potential of this product, but we recognise that it is selling into a market segment that is commonly grant funded, so the selling cycle is characteristically long. That said, as we sell direct, our margin is substantial, and strong profits can be generated from low volume sales.

### **Carl Zeiss**

Leveraging the progress we had made in clinical pilot trials in rigid endo-microscopy, we were very pleased to conclude our first deal in this area with the Carl Zeiss Group. Zeiss are a global company based in Germany with numerous market leading businesses several of which are dedicated to serving medical markets. The ZEISS brand name is recognised worldwide for excellence in high quality optical and opto-electronic instruments.

Carl Zeiss are the global market leader in research confocal microscopes so it is a testament to our technology that they would step up to licence our miniaturised confocal systems in order to introduce endo-microscopes into one of their key medical markets.

We signed the deal with Zeiss in very early July and are now getting down to detailed project management, prototype specification and clinical trial planning. It is early days yet, but the project is characterised by great enthusiasm by both companies and participating doctors. We are finding their overtly application led market and instrument development processes refreshing and positive and believe they are well suited to securing good technical, medical and commercial outcomes.

### **Product Development Pipeline and Revenue**

It is entirely appropriate for us to focus on our commercial directions and achievements with our current products, but we must not overlook the importance of ongoing investment in continuing product design and development. Over the past year, as our R&D team has been progressively released from the demands of the Pentax ISC 1000 work and we have been able to dedicate time to the development of a second generation platform. This will produce a smaller, stronger, faster, lower cost operating system capable of seamlessly integrating into the fully digitised clinical operating theatre environment that is rapidly being implemented in hospitals worldwide. This platform will be the basis of several new product developments, including those of Pentax and Zeiss.

Importantly it will also significantly increase the attractiveness of opportunities available to Optiscan to pursue commercialisation of proprietary own branded products in selected areas of the rigid market.

From the current financial year our product development capabilities will create a new revenue stream for Optiscan. Payments for undertaking product development is a feature of both the Pentax and Carl Zeiss agreements reached during last year. When these payments are combined with research grant funding our business now will feature a sizeable revenue stream from ongoing development activities.



## 5 Year Review

I would now like to adopt a somewhat longer timeframe and address the significant progress your company has achieved over the past five years. I believe this longer timeframe is useful to understanding what our company has achieved and more importantly where those achievements will take it moving forward.

In 2002 when I joined Optiscan, we had just concluded a collaboration agreement with Pentax, and our miniaturised scanner was at prototype development stage. We were full of optimism and confidence, but we still needed to navigate a path that turned technology into medical product, showed efficacy in the clinic and secured sales and commercial success. In addition many of the capabilities we needed were still in their infancy or non existent.

In 2003, the new board put a commercial strategy in place, and identified key milestones to chart our progress. We intentionally focused our resources onto flexible endoscopy to miniaturise our technology for medical use knowing that the platform created would open up opportunities in rigid endoscopy. That year we developed the world's first fully functional prototype flexible confocal endo-microscope which Pentax exhibited at the Digestive Diseases Week Congress (DDW) in the USA.

In 2004, we achieved quality accreditation, and commenced clinical trials in several leading hospitals around the world with Pentax. Working closely with leading doctors we helped them demonstrate outstanding clinical efficacy thus revealing the full potential of our technology. Findings were published in the leading peer reviewed journal *Gastroenterology*.

In 2005, we achieved the essential regulatory clearances with CE Mark for Europe and FDA clearance for the USA. Pentax also conducted initial market launch activities for the ISC-1000 at DDW. Internally our R&D engineers steered the product development from prototype to final design and we developed initial production.

In 2006, Pentax launched the final product ISC 1000 onto the world market while we manufactured and shipped to Pentax the first truly commercial sales quantities of system control boxes and miniaturised scanners. We dramatically improved our manufacturing infrastructure to ensure consistency of production. We also increased our focus on accessing rigid endo-microscopy commercial opportunities by successfully conducting clinical pilot trials in selected applications.

In 2007, we achieved record sales and made a solid profit from the Pentax focussed product sales segment of the business. We entered into an agreement with Carl Zeiss that will see us design and produce an entire endo-microscope instrument. We also released built and sold our first own brand instrument the Optiscan FIVE1 and in so doing put us for the first time in complete commercial control of all aspects of an entire product stream.

Throughout this period the work pace at Optiscan has been hectic and has required timely and frequent management decisions at every level of the company. Throughout we have maintained strong momentum, worked hard to overcome setbacks and learn from our experience while keeping an appropriately strong focus on delivering the strategy.

These achievements have delivered a technically great product, the capabilities to make it, demonstration of truly exceptional clinical efficacy and good commercial progress - albeit the unanticipated current issues with Pentax/Hoya are a setback.



Importantly Optiscan's evolving business model has now matured to the point where we can derive value from several different market streams. Some streams such as flexible demand a combination instrument so we must partner, as indeed we have. However, some segments of the market for rigid endo-microscopes demand instruments that Optiscan can make and even brand itself. Pursuit of these opportunities will enable Optiscan to capture far more margin from instrument sales. More importantly it will give Optiscan full control of market development activities and hence commercial outcomes.

I will very shortly hand over to Peter who will provide a description of the opportunities that are now accessible for our technology, including a set of opportunities in one value stream suitable for Optiscan to build and brand its own medical instruments.

In concluding my remarks, I would like to take this opportunity to extend my thanks to you and all our shareholders, to my colleagues on the board and to all the staff of Optiscan. Thank you for both the opportunity to serve as CEO of this company, and for your support throughout the last five years.

The path to success with medical technologies carries great highs and lows, and along the way we have all shared moments of elation and disappointment. Together we have achieved a lot over the past five years, due in large part to the dedication and desire for success displayed by everyone in the company.

Optiscan is a great company, with talented people and a unique and highly efficacious technology that has substantial market opportunities. We have put out technology firmly on the world stage and are now the global leaders in our field. Optiscan has all the key ingredients needed to succeed and I am absolutely confident it will.

Thank you



## **Director of Technology AGM Address 2007**

**Peter Delaney**

Thank you Matthew, and now I would like to provide a review and update of clinical trial activity and plans across our flexible and rigid product developments.

A mature understanding of just what we are seeing with endomicroscopy in patients has underpinned strides forward in training, new application development and clinical trial designs to establish the real clinical benefit.

Despite the frustration we're experiencing with Pentax sales of the flexible endomicroscope, the position of endomicroscopy in the medical field of gastroenterology has continued to grow and strengthen.

The number of applications of endomicroscopy has continued to grow, as shown on this list, with over a dozen indications that have been investigated clinically, including upper and lower endoscopic procedures:

- Barrett's oesophagus and surveillance for Barrett's Cancer
- Oesophageal squamous cell carcinoma
- Non-erosive reflux disease
- Reflux esophagitis
- H.pylori
- Gastritis
- Gastric intestinal metaplasia
- Gastric cancer
- Celiac disease
- Ulcerative Colitis
- Colorectal Cancer surveillance
- Microscopic colitis
- Graft Versus Host Disease (GVHD)
- Pouchitis (in colectomy patients)
- Pediatric

I will not attempt to cover each of these in detail, as most of them have been reported previously and published in the scientific literature, but draw your attention to the fact that there have been key new developments, such as the introduction of our technology in the field of paediatric endoscopy.

Dr Mike Thomson in Sheffield, UK been using endomicroscopy for endoscopies in children as young as 12 months of age. He feels that the ability to diagnose in vivo and proceed directly to treatment has vast implications in paediatrics, a field where eliminating separate follow up endoscopies would have huge benefits.

During the year, a steady stream of publications has emerged in reputed peer reviewed medical journals from investigators around the world. As a result, the growing body of scientific data supporting the efficacy of confocal endomicroscopy attained even greater visibility to gastroenterologists and other endoscopists.



Too numerous to list individually, in summary, note that there are now:

- Over 22 Peer-reviewed journal articles
- 16 Review articles and editorials (which is a high number relative to the original research publications, indicating the significance to the field).
- 4 Book chapters
- >150 conference presentations (to the extent it is difficult for us to know all of the conferences where endomicroscopy is presented)
- 1st Dedicated text book

I would especially like to draw your attention to three particular articles of note.

The first text book atlas of endomicroscopy was finalised during the year. The sections of this key reference text book were contributed by expert authors in Europe, USA, Australia and Asia. The comprehensive collection of reference images and diseases covers all sections of the gastrointestinal tract (both upper and lower). It also covers the decisions facing the endoscopist, and the way in which endomicroscopy can be applied to benefit the procedure. As such, it reads more like a general text book of GI pathology, except here it is described using our technology. The atlas is due to be released for sale January 3<sup>rd</sup>, 2008.

Secondly, a German clinical study of cancer surveillance in ulcerative colitis patients was published in *Gastroenterology*, the top journal in this medical field. Although not the first published work in this topic, this study broke new ground because of a powerful randomised prospective design. This allowed the standard of care procedure to be compared side by side with a modified procedure in two groups of patients. Importantly, the modified procedure involved using endomicroscopy in place of some biopsies with the goal of dramatically reducing the number of biopsies normally required

The results were stellar, finding that endomicroscopy increased the diagnostic yield per biopsy for neoplasia (early cancer) by 475% (nearly five times the yield) and offered a 90% reduction in the number of biopsies. So, this result showed not only that endomicroscopy could be used to predict the outcome of biopsy, but that it could be used to improve the overall efficiency and outcome of the endoscopy.

A similar confirmatory study has recently been completed in the UK, with results presently being prepared for publication.

Based on this progress, the study design has now been finalised for a European multicentre study with the aim of influencing the guidelines for the standard of care if the result emerges consistently across multiple hospitals participating in the study.

Finally, numerous review articles appeared in various medical journals, which bring together the data from individual studies across all of the applications listed earlier and puts them into perspective for easy access for gastroenterologists. Many of these have appeared in high impact journals such as *Gastroenterology* and *Nature Clinical Methods* with key commentary on the implications for endoscopic practice, such as the quote shown here –

*“In vivo analysis with endomicroscopy of circumscribed stained lesions can significantly reduce the total amount of biopsies per patient with a simultaneous increase of the diagnostic yield of intraepithelial neoplasias. Thus, the time of untargeted biopsies should be finally over.”*

GASTROENTEROLOGY 2007;133:742–745



Although Pentax's sales momentum in the US has been extremely disappointing, there has been slow but significant progress in the establishment of key centres that will serve as the market development foundations for the region.

Compared to the distribution of sites we showed last year, which included the establishment of the number one hospital in the US, Johns Hopkins Hospital in Baltimore, as a key centre for endomicroscopy...

...There are now sites in Phoenix, Tucson, Texas, New York, Boston, and others. The calibre of institutions is absolutely first rate, including Johns Hopkins, Mayo Clinic, Massachusetts General Hospital, MD Anderson cancer centre (the largest cancer centre in the US) and New York Presbyterian (recently announced the number one hospital in New York State. Several more are also now queued up to join.

We expect that consequently the amount of US experience and internal advocacy is well placed to underpin US multi-centre trials, training and other US market development efforts by Pentax.

There are now 4 training centres globally, again more concentrated in Europe, but we are involved with Pentax America's plans to extend training infrastructure based on this emergent network of leading hospitals.

In Europe, which is far further progressed in market development than the US, the training centre in Mainz Germany is now running ten courses per year including hands on training as well as theoretical sessions on image interpretation. The courses are fully subscribed well in advance, training over a hundred endoscopists in the past twelve months. Details of the Mainz course can be found on the associated education website, [www.endomicroscopy.org](http://www.endomicroscopy.org).

More recently, the UK's Academy of Endomicroscopy at the Royal Hallamshire Hospital in Sheffield, UK also began running courses. The program is run by Dr Paul Hurlstone, based on his experience in well over 1000 endomicroscopy procedures performed. Dr Hurlstone was recently awarded a prestigious Medical Futures Innovation Award for his use of endomicroscopy in cancer prevention.

Now I would like to cover our activities towards commercialisation of our rigid endomicroscopes in several areas of application.

It is fair to say that progress and technical success in flexible applications has greatly facilitated our concurrent efforts in rigid applications, both at the level of our own understanding of our technology's benefits and in terms of awareness of the technology in the broader medical community.

As I will come to in a moment, we are tracking a diverse field of potential applications of our technology in rigid endoscopic form, and the challenge is to prioritise and commercialise winners.

Our process for determining the best application areas to pursue as products is based on numerous commercial and technical parameters. Medical need, procedure volumes, health economics, customer buyer behaviour, available sales channels and the technical fit of endomicroscopy to meet the medical need are all carefully considered.

High procedure volumes and medical need combined with medical specialties that utilise major capital equipment make for desirable application areas.



So for example, in this chart we see over 35 potential rigid applications that we have researched as potential candidates for clinical investigation or commercialisation. This is clearly more than Optiscan would pursue, although with time, we may build a portfolio of an increasing proportion of this map.

On this chart we have arranged the applications by increasing patient/procedure numbers, and vertically by medical need (which drives pursuit of new technology). This gives a preliminary indication of the market potential.

Next, we focus on applications that we can commercialise now with the technology we have already developed or is well in hand.....

....and this reduces the field to just over 25 possible areas. Finally we can further tier the possibilities by considering the buying behaviour and capital equipment infrastructure of the target medical field and the environment in which procedures would be performed.

So we see, for example, that while skin cancer applications represent an area of significant need in common diseases with large patient loads, they are performed in an environment that does not enjoy much in the way of capital equipment infrastructure. This is mirrored by a poor capital selling infrastructure and difficulty finding appropriate sales channels. Likewise, an application in cervical cancer would suffer the same obstacle if targeted to rooms based procedures, but becomes viable as a day procedure centre or hospital based procedure.

At the other end of the spectrum, robotically assisted surgical resection of prostate cancer, for example, involves high volumes of procedures performed in an environment that utilises multimillion dollar robotic equipment. Such procedures have a need for in vivo diagnosis of fine tissue structures that the surgeon is able to separate with the high precision of the robotic method.

We have used this process to identify a handful of applications for clinical investigation in recent times. We believe they all represent attractive market segments with good prospects that endomicroscopy will address real medical need, in market segments with good procedure volumes, strong capital equipment infrastructure and associated commercial framework.

As Matthew has just described, we have recently entered into agreements with Carl Zeiss of Germany to develop rigid endomicroscope products for certain applications. While Zeiss require us to keep their applications and market segments confidential at this stage, we are pleased to report that the project is very active both in terms of joint planning, product development activity, and initiation of clinical trials. We are excited by the target application areas and the collaborative and co-operative approach of our Carl Zeiss colleagues.

After several recent visits with Zeiss project team members at the lead clinical investigation site in the US, we have now formally initiated the process of seeking approval for the first clinical studies to be conducted in the near future. We are impressed by the enthusiasm and sense of urgency with which Zeiss have engaged this project, and note in particular that the clinical investigation plan is being pursued to reach product release milestones ahead of the originally agreed project plan.

This has been a significant year for conduct of clinical studies in new application areas. Given the rich array of possible applications, these "first time in human studies" have been critical steps in prioritising the areas for commercialisation.





In summary, this list includes the many new application areas recently entered into, or soon to enter into human studies.

- Rigid open surgery for pancreatic cancer – Sydney, Australia
- Rigid Mini-Laparoscopy for liver imaging – Mainz, Germany
- Bronchoscopy for airway inflammation – Philadelphia, USA
- Laparoscopy for endometriosis – Melbourne, Australia
- Rigid Handheld for cervical cancer – 3<sup>rd</sup> study planned, Melbourne, Australia
- Zeiss applications – USA site planned
- Robotic prostate surgery – 2 sites, East and West coast USA

There are some extremely exciting new applications areas now under clinical investigation or soon to be initiated, as listed here. Thus, in the near future we expect emerging data from these studies to drive new priorities for commercialisation both through partners (such as in Zeiss's market segments), and under our own brand.

One area I would like to cover in slightly more detail is Women's health.

We are presently undertaking detailed evaluation of a family of applications in this area, and we believe that these take advantage of key synergies in accessing certain patient demographics. These could be pursued via development of an Optiscan branded rigid endomicroscope system and would involve undertaking substantial market development activity performed in our own name. We believe this gives us maximum control over the establishment of these applications and would maximise the returns to Optiscan through increased profit margins.

I will now briefly overview the application areas.

Endometriosis is a prevalent Women's health condition affecting 10% of women of child bearing age in western society (or over 5 million women in the US) with healthcare costs exceeding US\$20billion. The condition involves growth of cells that are normally only found inside the uterus, but which have spread into the abdominal cavity, resulting in pain, scarring and even internal bleeding. Patients with endometriosis often undergo repeat laparoscopies (keyhole surgery), initially just to find affected tissue and establish a diagnosis, and subsequently to surgically remove affected tissue. However, given the poor diagnostic sensitivity of laparoscopy, and significant disease recurrence rates after therapy, we believe endomicroscopy has the potential to significantly improve the outcomes and economics of management.

Secondly, we will further our applications in cervical cancer. Optiscan has historically established the utility of earlier generation rigid endomicroscopes for staging of early cervical cancer, or CIN (cervical intraepithelial neoplasia). We are presently undertaking to continue studies in this area using the latest clinical grade rigid endomicroscope systems, which we expect to be even more efficacious. In particular, we would target the colposcopy procedure that normally follows from a positive Pap smear.

In the US alone, medical insurers pay several billion dollars per year for these follow up procedures (far more than the total market for the initial screening Pap smear itself). However the specificity of diagnosis from colposcopy is poor, and leads to controversial rates of therapy. We already know from our past studies that endomicroscopy can clearly visualise early cervical cancer. Upcoming trials will assess the impact that endomicroscopy could have on the specificity and overall effectiveness of follow-up colposcopy.



Finally, longer term opportunities exist in the Women's health arena. For example, the development of biomarkers for ovarian cancer (with several companies, some in larger Phase III clinical trials) may identify significant cohorts of patients that represent an indication for endomicroscopic laparoscopy.

The above three women's health applications would focus on accessing patients through women's hospitals or healthcare centres and thus would enjoy numerous synergies in commercialisation.

Establishing new products in new application areas takes time and resources. This must be, and is being pursued in parallel with ongoing market development activities for Pentax's flexible product.

However we are confident in these new applications because we have a strong understanding of what endomicroscopy can do. We have detailed market analysis of over 30 potential application areas, with several new applications prioritised for early clinical trials (many of which have begun). We have a focus on fast tracking the rigid endomicroscope for development from clinical grade prototypes already used in patients to product. We believe the company is well placed to increase the value captured from its technology by careful and selective pursuit of these opportunities.

Thank-you for your attention to this update, and I will now hand you back to our Chairman, Grant Latta.



**Other Business  
Grant Latta**

**Ladies and Gentlemen,**

**Matthew resignation**

I mentioned earlier that we must acknowledge not only Matthew's decision to move on, but more importantly, the significant contribution he has made to Optiscan.

As Matthew's address has outlined, there has been huge progress over the past five years.

He has led the company through a period where the technology has navigated development collaborations, regulatory clearances, quality certification and release on the global market.

He has established opportunities in rigid endoscopy, and has delivered our first own brand instrument, the Optiscan FIVE1.

We are all aware that our technology is destined for the world market.

That means many of our staff must sacrifice personal interests and family commitments and engage in often long and gruelling travel schedules.

Some staff more than others are subject to this imposition and few more so than the CEO.

Matthew has a young family, and over time, the demands of this aspect of his job have weighed heavily on his mind.

He has ultimately arrived at a point where, unfortunately, the decision became quite clear.

We would prefer that this point had not been reached, but it has, and we must respect his decision to give priority to his family.

We thank Matthew for the leadership he brought to Optiscan and for the progress achieved during over the past five years.

We will now turn to the formal business of the meeting.

**Accounts and Reports**

Before dealing with the resolutions set out in the Notice of Meeting, we will first consider the accounts for the year ended 30 June 2007, together with the reports of the directors and auditors.



Although there is no formal resolution to be considered, I invite any questions you may have on the accounts and reports.

Also, if you have any questions relating to the audit report or the conduct of the audit, I can direct those matters to the auditor, Mr Don Brumley.

We will now move to the items of business requiring a resolution of members.

## **PROXIES**

The company has received proxy votes totalling 29,318,633 shares, representing 28.14% of the issued capital.

I declare that the proxies as tabled before the meeting comply with the requirements under the constitution of the Company.

In relation to proxy votes, I advise that undirected proxies will be cast in favour of the resolutions.

Finally, when voting on the items of business, I would ask all shareholders and proxyholders to raise the blue admission card.

We will now move to the first resolution.

## **RESOLUTION 1: Adoption of Remuneration Report**

This resolution deals with the remuneration report included in the directors' report.

You will be aware that this is a requirement of the Corporations Act.

It is a non-binding resolution.

Of the total proxies received, 99.4% representing 29,135,694 shares were in favour of the resolution or appointed the Chairman to vote on their behalf.

180,189 votes representing 0.61% were against

Are there any questions relating specifically to the motion that is, questions relating to the remuneration report.

I will now read the resolution

'That the Remuneration Report included in the Annual Report for the year ended 30 June 2007 be adopted.'

I put the resolution to the meeting.



## **RESOLUTION 2: Re-election Keith Daniel**

This Resolution deals with the re-election of Mr Keith Daniel as a director of the company. It is an ordinary resolution requiring a majority vote.

Some biographical background on Keith is included in the Annual Report, and in the Notice of Meeting, but I would like to take this opportunity to add a few comments of my own.

Keith has served on the board since August 2001. His extensive experience in the Australian medical device industry places him in a unique position to provide wise counsel to the board and management.

He has an engineering background, and is highly literate with the technical issues that come to the attention of the board.

Equally, his experience extends into areas of marketing, product management, sales structure, and after sales support.

He provides the board with vigorous and independent views on a range of issues. I know his input is highly valued by his colleagues on the board and in the management team.

The nomination Committee has endorsed Keith's re-election.

I commend the resolution to you.

In relation to proxies, 82.78% of those received representing 24,268,385 shares were in favour of the resolution or appointed the Chairman to vote on their behalf.

5,050,248 votes representing 17.23% were against

I will now read the resolution

That Keith Daniel, a Director retiring in accordance with the Company's constitution, being eligible and having signified his candidature for the office, be re-elected a Director of the Company.

I shall now put the resolution to the meeting.

Ladies and gentlemen, the formal resolutions have now been completed. We will now deal with any questions.

## **CLOSURE**

There being no further business, that concludes our annual general meeting. I now declare the meeting closed and thank you for your attendance and participation.