Pharmaxis Ltd

Annual General Meeting
17 October 2012
Sydney
Chairman's Address by Malcolm J McComas

At this meeting last year, long term Chairman Denis Hanley said: "...in 2011, we have been able to create a strategic foundation – one that is now set to return value to shareholders over the long term." In 2012, the Company has made substantial further progress to that goal, but it wasn't just as we had planned.

In calendar 2011, the failure to achieve European approval for Bronchitol set us back twelve months. The European marketing approval we were subsequently granted on 20 April 2012, on appeal, was a cause for modest celebration.

In Australia, where TGA approval was granted in February 2011, (some fourteen months after our application was filed), we were further encouraged with a grant of reimbursement under the Pharmaceutical Benefits Scheme (PBS) with effect from 1 August 2012. This process also took longer than we had planned. Both these approvals demonstrate the complexity, timescale and difficulty of the task we have undertaken and are achieving.

The regulatory pathway and the reimbursement processes in all the global, regional and national markets that we aspire to operate in are the current challenges for Pharmaxis. This is a step change for the company whose primary focus to date has been the design and management of clinical trials for Aridol and Bronchitol. We look forward to closing and then announcing results from the B305 trial of Bronchitol for Bronchiectasis in the second quarter of CY2013, something I hope to comment on next year.

In the United States, our filing of a New Drug Application (NDA) for Bronchitol in May 2012 was another major milestone. Our submission was accepted for review in August and the end date (the PDUFA date) for the review is 18 March 2013. If European approval on Appeal was the cause for modest celebration, the leadership team and staff of around 150 (and our shareholders) should be overwhelmed if we receive a green light from the FDA. But experience has taught us that approval can be delayed while we satisfy the regulators requirements – sometimes with associated incremental cost.

The FDA's process is fundamentally different to that of the EU. The FDA's field team are currently visiting CF clinical trial sites and they have recently inspected our manufacturing facility at French's Forest as part of their review of our NDA.

We expect to shortly receive advice of the date for a public hearing, expected to be in late January 2013. This will afford a good opportunity for the FDA convened advisory review panel to hear from and engage directly with CF patients, clinical advocates, key opinion leaders and the broader CF

community in addition to the clinical, safety and manufacturing information contained in our 208,000 page submission.

The other part of our focus this year has been the preparation and launch of Bronchitol in Europe and Australia. In Europe, where we are approved for patients 18 and over, we launched in Germany and the United Kingdom in June. This was followed by Austria and Denmark in July and August. In Australia, reimbursement gave us a proper launch platform from August. The second wave of European market launches starts in the first quarter of 2013 - France, Italy, Sweden, Netherlands, Ireland, Spain, Portugal and Belgium – and will follow reimbursement approvals in those territories. Thereafter, the focus shifts to other non-European markets and label expansion into adolescents and children.

Sales to date are modest but the momentum is growing nicely. The process of inducting new patients onto a new medication is also complex. It involves education of clinical staff, patient training and product distribution and we provide this through the field force of our sales partner Quintiles and our logistics partner Arvato.

The board gets to see the sales progress weekly. We have KPI's set to measure progress and achievement. With the benefit of hindsight, sales volumes may probably prove to be wrong in the short term. However, we are encouraged by the very early signs of product acceptance by clinicians and patients that is starting to emerge in our first few markets. Hopefully this will continue but, again, the pathway won't be straight and there will be challenges to overcome – I don't know what or when but from experience, there will be challenges to overcome.

Director Will Delaat undertook an "on the ground review" of our market readiness in Europe in May and I visited our small European office (in Slough) in July. The board is very involved in this transformation from drug developer to a sales and marketing and manufacturing business based in Sydney serving global markets, owning 100% of the product.

Our sales achievements should be measured in years and not months or weeks. It is not meaningful to provide guidance at this stage. We will of course keep you informed through the Quarterly Report as we see trends developing and as new markets are opened up.

We are also looking at ways to ensure we maximize the value of the Bronchitol franchise in the medium term. However, the value of this business opportunity is directly linked to the outcome of the NDA process.

As you can gather, the leadership team has had a busy and productive year. We have a very strong leadership team for a business of our size – four of our seven senior managers have relevant international experience with major pharmaceutical companies. The remuneration report sets out the details of the compensation paid and the amount of compensation that the team have at risk. The performance and the payout of the at risk component were materially higher than in FY2011.

There were also some modest changes to the amount of director compensation within the current cap that you approved in 2006.

During the 2012 financial year, outside of the six scheduled formal meetings, the board met on an additional eleven occasions and continues this practise of more frequent meetings to keep everyone

in touch with the business, the management team and the big commercial outcomes that we are seeking. That will continue in 2013. We plan to meet more frequently than in the past and that is due to the increasing complexity of the business, as we seek to grow the revenue line, something quite new for Pharmaxis.

Thank you also to the directors for their contribution. We have good global representation, a mix of complementary skills and a commitment to create meaningful returns to shareholders as the business transitions to sales and revenues.

MJ McComas
Chairman
Sydney
17 October 2012