Pharmaxis Ltd

Annual General Meeting
27 November 2013
Sydney
Chairman's Address by Malcolm J McComas

Good afternoon ladies and gentlemen, shareholders and guests.

Developing new pharmaceuticals is known to be both a challenging and rewarding process. Like all who commit to the process of researching and developing new medicines, we have each year encountered regulatory delays and setbacks in some area of our business. The 2013 year has however been a most difficult one for Pharmaxis.

It is appropriate that I highlight some of the difficulties we faced and provide some context as to how the Board and management have responded.

At the beginning of the 2013 financial year, the company was proud to have reached the stage of being able to launch our Australian invented cystic fibrosis drug *Bronchitol* in Europe and Australia after more than ten years of development. The opportunity to launch a new product is a rare one for an Australian drug development company. Pharmaxis has created the product, and as significantly, the sales, regulatory, reimbursement, safety, manufacturing and corporate infrastructure to deliver *Bronchitol* to patients across Europe and Australia.

The initial sales trajectory for Bronchitol was not what we had hoped. This was due to a number of factors, primarily delays in obtaining the necessary reimbursement approvals across Europe and also patient adherence issues specific to German cystic fibrosis clinics.

However, we successfully obtained a positive recommendation from the UK NICE, arguably one of the more stringent pricing authorities in the world and it has been pleasing to see the steady growth in UK sales since this recommendation became effective in April 2013.

In Germany, we have worked with the cystic fibrosis clinics to develop an innovative pilot patient support program and the initial feedback is encouraging.

In France we were unfortunately not able to secure an acceptable reimbursement price with the French Healthcare Products Pricing Committee and therefore significantly scaled back resources we had dedicated to the launch of Bronchitol in that country.

Closer to home we worked with the local cystic fibrosis community to have the Australian PBS guidelines modified to be better aligned with clinical practice and make Bronchitol more easily available to qualifying patients.

It was, however, the negative vote by the US Food and Drug Administration's advisory committee in January 2013 and the subsequent advice in March from the FDA that Bronchitol is not able to be approved for the United States that had the most significant impact on the company. This was the catalyst for the revised business plan announced at the end of May.

It was during the development of this plan that founding chief executive officer Dr Alan Robertson indicated his wish to resign in order to focus on early stage research. Alan continues to be involved in mentoring our R&D program. I wish to acknowledge and thank Alan for his significant achievements in leading Pharmaxis for 13 years, 10 as a listed company.

Due to the risk inherent in regulatory processes, it was decided early in the 2013 financial year that the Company should investigate a range of non-equity alternatives to either fund the business in the event of an unfavourable FDA outcome or assist in the US commercial launch in the event of a favourable outcome. The NovaQuest investment of up to US$40 million announced in January is an innovative financing mechanism that brings forward some of the value of Bronchitol – enabling the Company to pursue US approval.

The business plan developed after the FDA's decision was thus able to be built around a strong cash position. Gary and his senior management team worked hand in hand with the Board to develop a plan designed to deliver a US approval for Bronchitol; a growing revenue for our approved CF markets; and an ongoing strategic interest in our early stage pipeline, all within existing financial resources.

The plan was not just about cutting costs although we are on track to reduce our cost base by the planned 30% by the end of 2013. Rather, over a fairly short period of time, the plan seeks to explore the commercial merits and value of various funding alternatives that can be expected to crystallise value across the business. While not yet complete, we are on track in that review phase.

The appointment of Mr Gary Phillips as chief executive officer was another key decision. We believe that he has the leadership qualities necessary to make tough decisions and drive organisational change. Gary describes himself as "a problem solver" and a "builder". The Board has seen this demonstrated as Gary brings his significant international pharmaceutical experience and his knowledge of the Company and the patient communities we serve to the task at hand.

Remuneration policy is particularly important in more challenging times when the people you most want to retain and incentivise are typically the most valuable and sought after in the pharma employment market place. The Board utilised the 2013 grant of performance rights to provide for retention and importantly, incentives that are tied to successful delivery of the business plan. The granting of performance rights to the chief executive officer is an item of today's formal business.

At the Board level we have remained very engaged with Gary and his team. Over the last year we have averaged 2 meetings a month as either the full Board or a committee, in addition to individual director participation with management in applying various areas of director expertise. Once the business plan was developed and launched, it was appropriate to reduce the size of the Board and Dr John Villiger and Mr Richard van den Broek retired in September. I thank both of them for their insight, contribution and years of service.

Your board remains determined to rebuild confidence and value for Pharmaxis shareholders and we believe that 2014 will be a productive year for the Company. We appreciate your support and thank you for attending.

MJ McComas
Chairman
Sydney
27 November 2013