Pharmaxis Ltd

Annual General Meeting
27 November 2014
Sydney
Chairman's Address

Good afternoon ladies and gentlemen, shareholders and guests.

As I have just advised the meeting, Malcolm McComas is unfortunately unable to join us today and has requested that I assume the role of Chairman of today's annual general meeting and deliver this address on his behalf.

You will recall that in 2013, following advice from the FDA that Bronchitol was not able to be approved for the United States at that time, the Company developed a plan to redefine the Pharmaxis business model. The plan sought to achieve:

- a US approval for Bronchitol;
- continued growth in revenue for our approved CF markets outside of the US;
- a reduction in costs;
- the partnering of our assets; and
- the selective development of our early stage pipeline to support funding initiatives,

We have expanded on this plan and, in addition to pursuing a partner for Bronchitol in the US, we are actively engaged in discussions to partner Bronchitol in the EU. Our ongoing Bronchitol business will then focus on completing the clinical trial required for US approval and the manufacture of product for global markets.

In relation to the Company's early stage pipeline, as I will further explain, after an extensive review of the landscape for assets at a comparable stage of development, we have determined that we can and should maximize the value of these assets by retaining them until early development milestones are achieved rather than partner too early. Fortunately, one of our early stage assets is very close to that now.

By the end of the June 30, 2014 financial year, we had made substantial progress and expected that a US partnering of Bronchitol, the foundation of our plan, would soon be in place. The decision by the Company's financier in the first week of the new financial year to allege a breach of our financing agreement was a significant setback to all of our plans.

Rather than completing the Bronchitol partnering and then moving to deliver on other aspects of the business, most of our corporate efforts have been directed at renegotiating the agreement with our

prospective Bronchitol partner to incorporate funding of the Phase 3 clinical trial required for US approval.

We have made significant progress in these Bronchitol partnering negotiations and are currently working towards the completion of a binding agreement before the end of the calendar year. Overall however, we have lost about six months.

While these matters have been at the forefront of our corporate activity since the end of the financial year, it is appropriate that I highlight some of the achievements and detail the difficulties we faced during the year itself.

Key to accessing the US cystic fibrosis market is completion of the Phase 3 clinical trial required by the US FDA. We refer to this trial as the CF303 trial. The US CF market is the largest opportunity for Bronchitol and is characterised by excellent support and management of cystic fibrosis patients in line with the UK, but also with excellent reimbursement support by US healthcare funds. We expect this to translate into faster adoption of Bronchitol than we have experienced in any other major country and adherence to therapy that is comparable with the UK market.

During the year we completed the design and detail of the clinical trial protocol for CF303, submitted it to the FDA for their review - and incorporated their comments. We are in quite a unique situation with CF303 in that we are conducting a trial with the benefit and confidence of two prior Phase 3 trials of very similar design both of which achieved a positive outcome in the patient sub-group we are now studying - 18 years and older. To further increase the probability of achieving a statistically significant result, we plan to recruit up to 440 adult patients, compared to 150 adults in each of previous two trials. On completion of a successful study, we will not need to resubmit an entire new drug application – as our application for approval will be based around the NDA we have already filed.

Earlier this year we concluded a tendering process for management of the study and appointed the clinical research organisation INC. They have since set about the large task of commencing a study that includes more than 100 sites across 20 countries. While the study was delayed because of funding uncertainty, it was pleasing to have the first patient into the study earlier this month. The study will take around 12 months to recruit and patients are in the study for 6 months so we expect to have the results in mid-2016.

On the sales front, Bronchitol is now approved and reimbursed in Germany, Denmark, the UK and Australia and sold on a named patient basis in several other EU countries. We are also approved and currently negotiating reimbursement applications in Ireland, the Netherlands, Italy and Israel, and we are progressing approval applications in Russia and Brazil.

We had year on year sales increases in all three of our major markets (Germany, UK and Australia). Both UK and Australian sales have continued to grow as pricing hurdles and constraints were overcome by the Company. In Germany, while new patients are being treated, compliance to Bronchitol therapy is less than optimum, and so we have not seen the continued growth that was envisaged given the size of the opportunity. We know that the impediment is patient adherence and we have been actively pursuing patient support programs in the major German CF centres.

Since the beginning of the 2014 financial year, we have been conducting a comprehensive program to partner or otherwise fund our early discovery programs, in particular the LOXL2 and SSAO programs. We have spoken to a wide spectrum of international pharma companies including the large well-known names. One of the reasons Gary is not here today is that he is meeting with a potential partner tomorrow. We are convinced that both of these programs are very valuable to Pharmaxis and can provide an important increase in value to shareholders.

Our LOXL2 program is focussing in an area of significant interest to large pharmaceutical companies, and our discussions lead us to believe our approach is unique and potentially first in class. LOXL2 plays a role in several fibrotic diseases and some cancers. However, while the level of interest from potential partners has been very encouraging, the current lead optimisation phase of the program is still early and we must therefore balance the opportunity to attract a partnering deal now versus continuing a modest internal investment to advance the program to a point of greater value. Our preference if possible is to pursue the latter. We believe we have the financial resources and skills to do so in a timely manner.

By contrast, after completing the necessary toxicological studies on our SSAO inhibitor (PXS4728A), it is now ready to proceed to Phase I studies in man. This major achievement was announced in August and is a significant value inflection point. Around the same time, our partnering activities identified a number of companies that have shown interest in the effect of inhibiting the SSAO enzyme in several fibrotic and inflammatory diseases. The scientific interrogation of our data on PXS4728A by these companies is intense and we remain optimistic of an outcome that will not only see it go into full clinical development for a major disease, but also generate the funds needed to further prepare the LOXL2 inhibitor for full clinical development. We expect to receive term sheets for PXS4728A this quarter.

Our CFO David McGarvey will provide detail in relation to our reduction in the Company's cost base. In summary however, we achieved our initial objective of reduced cash costs by March of this year.

While completion of partnering deals in the US and EU will enable us to again reshape the business in a material way with reduced cash costs, all through this year we have been continuing to reduce costs as aggressively as possible. Indeed, in the current half year four of the senior management team have or will depart, along with other support staff.

I appreciate that shareholders may have questions about our litigation with NovaQuest. As we have stated publicly, the Company rejects NovaQuest's allegation that Pharmaxis breached the financing agreement and on 1 August 2014, the Company filed a lawsuit against NovaQuest in the Supreme Court of the State of New York to protect its position. Given the ongoing legal proceedings I do not propose to provide any comments additional to information already disclosed. We continue however, in what we assess as constructive discussions with NovaQuest to seek a commercial resolution to the matter, a resolution that fits with the US and EU partnering agreements currently being negotiating.

The Board would like to specifically acknowledge the effort of the CEO Gary Phillips who has worked with diligence and determination to pursue the Company's objectives in the face of some very challenging situations.

At the Board level, we have remained very engaged with Gary and his team this year. In addition to our scheduled monthly meetings, we have regular supplementary updates via phone and email. In July and August for example, we averaged two meetings a week. We reduced the number of non-executive directors from five to three in September of last year, and from January we also reduced directors' fees in line with other cost-cutting across the organisation.

In closing, I would like to assure you that the Board remains committed to overcoming the material obstacles that have confronted the Company over the last two years in order to enhance shareholder returns. While not always visible from outside of the Company, our progress over the past year has been substantial and we believe the Company is now close to delivering value for Pharmaxis shareholders. We have not yet arrived where we need to be, but we believe we are close. We remain firmly focussed on the path to partnering Bronchitol, gaining approval in the US and to realising value from our innovative research work. We appreciate your support, acknowledge it has been a longer and a more complex task than we had predicted this time last year but we remain convinced that we are on the right path to create shareholder value over the coming months.

Thank you for attending.

William Delaat
Non executive director
Sydney
27 November 2014