

**Title of conference call:** End of Calendar Year/December Quarter trials update and financial results.

**Date:** Friday 9<sup>th</sup> February, 2007. 8.30am Australian Eastern Summer Time

## **Script**

### **ADR:**

Good morning, good afternoon, good evening and welcome. My name is Alan Robertson and I'm the Chief Executive Officer of Pharmaxis; I have with me David McGarvey, Chief Financial Officer and Company Secretary and Jane Sugden from investor relations....This is the first conference call for 2007 that we have broadcast publicly and we will make it a regular quarterly event from here on.

First of all the safe harbour statement that covers Forward-Looking statements - **Portions of this conference call may contain forward-looking statements concerning the future business, operating results and/or financial condition of the company, as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on our current expectations and are subject to a number of uncertainties that could cause actual performance and results to differ materially from those anticipated by such forward-looking statements. For more information about these risks, please see the documents that we file from time to time with the Securities and Exchange Commission. In addition, any forward-looking statements represent our view only as of today and should not be relied upon as representing their views as of any subsequent date. We do not assume any obligation to update any forward-looking statement.**

We released the Quarterly Report to shareholders yesterday, and I don't intend to go over what has been included there other than to review the highlights for the quarter. I will then discuss the key aspects I see influencing our business in the future.

I'll discuss Aridol and its regulatory progress in Europe and the US, our marketing and distribution arrangements in Europe.

I'll then discuss Bronchitol - including the recently closed phase III bronchiectasis trial and the cystic fibrosis trial programs.

### **Highlights for the quarter –**

This quarter we have put behind us several important milestones, including:

- ❑ regulatory approval for Aridol in Sweden, and we have filed for approval in 14 other European Union countries
- ❑ We have opened new sites in Argentina to recruit the remaining patients needed to complete the cystic fibrosis dosing study
- ❑ We have completed recruitment for our Bronchitol phase III trial in bronchiectasis

- We have identified a further potential use for Bronchitol in acute care patients and have received the necessary approvals to begin a pilot study

We are now well positioned for the next phase of our growth.

To the first of the three topics:

**Aridol:**

The regulatory process is involved and complicated, and different in each of the major regions of the world. We are pleased to report that we are almost through Phase II of the European Union approval process.

The Swedish marketing approval was received in October last year, and the first wave of 13 European applications was filed immediately following the Swedish approval.

Our team was able to assemble documents for 13 European countries in 30 days — a third of the time normally required. The documents were filed with the various individual agencies on 22 November and officially accepted by all countries on 5 December.

We have received comments and questions from all of the 13 individual agencies and have filed our response with the help of the Swedish authorities. We hope to complete the end of the European Union review during the first quarter of 2007 and expect to have concluded negotiations with the sales/marketing and distribution partners in the outstanding countries very shortly. Sales can then begin shortly thereafter, although individual countries may come through at different times.

The Swiss application was filed in July and we expect to hear news from that agency very soon.

The marketing application process in the US will also begin shortly. Following the completion of the U.S. Phase III Aridol trial we have just held a meeting in the US with the principal clinical investigators and are assembling the study report. We expect to be in a position to hold a pre-NDA meeting with the FDA shortly and file the application in the middle of the year.

The registration and launch of Aridol in Europe is important, of course, and we are working with the key opinion leaders and our distributors to ensure a solid start to Aridol in Europe.

Europe account for about 35% of total global pharmaceutical sales, as compared to Australian sales which average about 2-3.

Sales of Aridol for the second half of 2006 amounted to \$117,000 and that figure includes sales in Australia; and in the US for a clinical trial with a US biopharmaceutical company; and to our partner in Sweden, Nigaard. Sales for the December quarter were \$68,000 – an increase on the previous quarter. Subsequent to calendar year end, we have received a second order from Nigaard. So the early signs are positive for Aridol in Europe. While Aridol is reimbursed in Australia under an existing treatment code we are

in the process of submitting an application for PBS listing which, if granted, will help the public lung function testing laboratories and should help with gaining traction. A product such as Aridol will take time before solid traction is achieved.

Our recent experiences in Australia with the marketing of Aridol will be of great value in Europe, and in the US. In Australia each state has different practices and different preferences in lung function tests: The variety is similar in Europe and different countries have their own preferences. In Europe, there is no approved products for direct or indirect testing – the interest in Aridol at a recent respiratory congress in Glasgow augers well for its future commercial health. We have appointed 6 distributors/marketing agents for Aridol to date – Nigaard in Scandinavia, Trimedal for Switzerland, Allertec in Greece, Italchimici in Italy, Romedic in the Netherlands, and Aldo Union in Spain. They have all been chosen with great care: their preparatory work, their specialist contacts, intimate knowledge of the local prescribing and testing practices, plus their access to the target market will be important in positioning Aridol.

### **Bronchitol:**

Bronchitol is our second product. Currently, we are conducting Phase 3 clinical trials for Bronchitol in both cystic fibrosis and bronchiectasis. Bronchitol is designed to improve the health of the lung in patients affected by excessive mucus build up. Bronchitol represents a more significant commercial opportunity than Aridol.

The Phase III Bronchitol trial in subjects with bronchiectasis has recruited its full complement of subjects. Over a 9 month period, we enrolled 354 patients from Australia, New Zealand, England, and Northern Ireland. This is a pretty good indication of the clinical need in this patient group.

The last of the trial subjects will now complete a three month treatment period. We anticipate the results from this trial will be available in the middle of the year. We have completed the preclinical and manufacturing aspects and I hope to be in a position to submit our Bronchitol marketing application in Europe during the second half of 2007.

Subjects who participated in the trial are being offered the opportunity to continue on Bronchitol treatment for an additional 9 months for those receiving Bronchitol and for 12 months for those that received placebo. The participation rate on this extension of the original study has been extremely gratifying.

Bronchitol has received Orphan Drug designation in the US for both CF and bronchiectasis.

The Phase III clinical trial programme for cystic fibrosis is scheduled to commence shortly in Europe and during the second half of the year in the US.

Bronchiectasis is classified as an orphan disease - a disease that afflicts about 600,000 people in the western world, and for which there is no approved therapy to help with mucus clearance. To our knowledge, Bronchitol is the only product in Phase III for this indication anywhere in the world. While recruiting for the trial we have had more than 5000 people requesting to join the trial – many of course did not fit our trials entry criteria for a number of reasons, but a common theme was the lack of an effective treatment for the congestion in their lungs.

We currently have a third indication for Bronchitol – patients with COPD – a smoking related disease. We have embarked on a pilot study in a small group of patients who have been admitted to hospital with breathing difficulties to determine if Bronchitol can assist this patient group. The results should be available during the first half of 2007. Last year in the US alone there were 1 million emergency room visits as a result of lung congestion associated with COPD. So, the commercial opportunity is significant.

Looking forward, our priorities are:

Marketing - Aridol sales in Europe and opinion leader awareness in the US

Regulatory - NDA filing of Aridol in the USA and completion of the European process

Clinical - Completion and data analysis from the Bronchitol bronchiectasis Phase III trial

Completion and data analysis from the CF dosing study

Commencement of the CF clinical trial programmes in the US and Europe

Thank you for your attention, and I'll now take any questions you may have.....

**Bret Holley (CIBC World Markets):** Hi. Question on Bronchitol, if the data from the phase two dose ranging trial in CF is important for setting the right dose for the US stage three trial, why were those data not important for the start of the European trial?

**Dr Robertson:** Good Question... the data is important. It's an open label study. We look at the responses from the patients in the trial. We've done a lot of work prior to the study that's currently being undertaken in Canada and Argentina: a lot of work that's not necessarily done to a regulatory standard. The European regulatory authority has accepted our earlier studies that indicate that we have the right dose. The FDA is more enthusiastic to see a regulatory standard study and that's what's going on at the moment

**Joseph Pagliaro (Wilson HTM):** Alan: a question on the progress of Aridol sales. Can you comment on any further progress in Sweden, what're your expectations for this half and the full calendar year and when you expect to see more material uptake in Australia?

**Dr Robertson:** Yes ...we're happy with the progress. In Australia we're getting really good signs of traction development. Australia of course is a small market as compared with the rest of the world and there are also different market dynamics to those else where. The product is definitely being embraced by the key respiratory physicians, also by the lung function testing labs who appreciate its convenience. Price of course is a sensitive issue here and less so in Europe. Sweden in particular is not a price sensitive market for us. Nigaard is our partner and their staff have been out here, and been trained in the product. They've placed their first order, and they've now followed up with a repeat order. So the early signs are good.

Here in Australia we've got around 50% of our key targets that we'd set and I'm happy where it is at the moment. It's all about going through an education process with the medical community. It's on track and meeting our expectations.

**Saul Hadassin (Credit Suisse):** G'day Alan it's actually Michael Chan from Credit Suisse. Just a quick clarification of the Bronchitol phase 3 in bronchiectasis. I understand after 3 months you'll get efficacy data. What's the process of registration after that 3 months?

**Dr Robertson:** I guess that's a question that relates to the part of the trial we refer to as the open label extension. You're right: the first component of the trial, (the formal part of the trial), is collecting efficacy data. That's available after the last patient completes their cycle. We closed the trial recently and in 3 months or so from now, the last patient will be through. We then have a follow up period after they come off the drug, and we look for data like rebound effects and other issues. That's really the formal close of the trial. We then assemble the study data and drop that into our technical document. We are preparing our marketing applications right now in the expectation of the clinical data when it comes through. Obviously, we want to take the opportunity to learn a little bit more about Bronchitol and how patients would react on a standard treatment. We'd like to see certainly upwards of a hundred patients complete 12 months of Bronchitol. In that component of that part of the study we are not gathering efficacy data, we're really interested in safety of the product and the patient's experience of the product. So, that's a long explanation. The bottom line is that in about the next two or three months from now, I'm expecting the last patient in, and then the clinical statistician to do what they have to do, and to be in a position to reap the results from the study.

**Michael Chan:** And with the CF phase three trial, I understand it's a similar sort of structure: 6 months of efficacy data and an extension period of 6 months. Does that mean you can start filing for registration after that first 6 months?

**Dr Robertson:** Absolutely. That's right. That's the way it works.

**Michael Chan:** And in terms of the phase two CF trial, you've had to go to Argentina now, do you expect the costs to blow out significantly because of that?

**Dr Robertson:** Well there are swings and roundabouts. You save costs from Canada as you haven't got quite the number of patients. The number of patients we need to complete this trial is actually very small: we've just exhausted our pool in Canada and I'm ready to open additional centres. We've got an enthusiastic response from Argentina. But yes, I expect the net cost of the trial to be a little more than budget, probably at the 8% level...

**Michael Chan:** And I've got a couple of questions for David if he's there? David just with the \$60 000 worth of outstanding orders that you mentioned, is that purely from Sweden or is it a combination of Sweden and Australia?

**David:** Well it's mainly Sweden. We have a very fast turnaround in terms of our orders coming in here in Australia. The order comes in here and the Aridol goes out nearly straight away. But export orders are much larger. They actually sit in backlog for a slightly longer period. So the answer to that is yes, its mostly in export.

**Michael Chan:** And I noticed the gross margin dropped a bit to 75%. Is that the expected long-run sort of level you're looking at for Aridol?

**David:** It's too early to give any expectations. Understand that when we bring in a European sale, what we're doing with our European distributors is selling them the product. The only cost we then have to incur is the cost of sales: we have no marketing costs therefore we do get a lower growth profit to start with. But it drops straight to the bottom line. So what you're seeing is the blended effect of Australian sales and export sales. If you like, its full customer standard price of which we need to wear our selling costs and the European export selling price where we don't have any selling cost. You'll see that bounce around for some time. It's a little early to be predicting trends off that number...but its where I expect it to be taking into account the blending.

**Saul Hadassin:** Alan this is Saul here. I just had one question to ask you if that's ok, just in regard to the Japanese review of the patent situation. I was wondering if you could update us on that and how you stand with Japan as a potential additional market?

**Dr Robertson:** Yes. I guess there's nothing much to say about that. The Aridol and the Bronchitol patent. The two outstanding territories that we haven't got the patent confirmed yet are Europe and Japan. Japan is in its final phase and they've been there for a while and there're significant questions at the end of the year. We've submitted our response and that's it I think: it's a normal process. The Japanese office or examiner wanted to limit the scope of the claim a little tighter than the US and the rest of the world but it's still obviously a solid protection for Aridol and Bronchitol, but perhaps less protection if we wanted to expand into other agents. It's not really a concern of mine.

**Graham Wald (Wilson HTM):** Morning Alan, Morning Dave. Could you just quickly run through the potential market opportunities you see for Aridol in the COPD Market?

**Dr Robertson:** I can point to some data that I'm expecting very soon now which seeks to prove or demonstrate that Aridol has the ability to identify those patients with COPD who have ongoing inflammation and to the extent in which patients will

benefit from inhaled corticosteroids. Given that I haven't got that data yet I can't really look forward too far in terms of giving you some feel or some reasoning. There's about one in five patients who respond to inhaled corticosteroids. But a lot of people with COPD don't seek treatment. From the way we look at things the management of asthma is a major opportunity. If we look at the revenue, the aspirational revenue that we have for Aridol, about 80% of it is in the asthma indication and about 20% is in the COPD indication. Perhaps it's too early to call a response.

**Graham Wald:** With the cystic fibrosis phase three trial in the US, once that kicks off would you be looking to apply for special protocol assistance from the FDA?

**Dr Robertson:** Absolutely. The special protocol assistance is a process that you go through in terms of a review process for the protocol. We've had some discussion with the FDA.

**Graham Wald:** Thank you.