
PHARMAXIS ANNOUNCES OUTCOME OF BUSINESS REVIEW

Pharmaceutical company Pharmaxis (ASX:PXS) today announced a revised business plan that delivers significant reductions in expenses and increases the focus on partnering strategies to grow the value of the Company's assets and reposition it for the future in the global respiratory drug market.

Pharmaxis will reduce the Company's March 2013 annualised cash cost base by approximately 29% and the annualised cash loss by approximately 37%. This includes extensive staff reductions and consolidation of manufacturing facilities with some cost cutting measures already being implemented.

The Company will seek partnership opportunities for Bronchitol in the US for cystic fibrosis (CF) and globally for bronchiectasis while retaining a direct commercial interest in Bronchitol in Europe and other approved and reimbursed markets.

In addition, Pharmaxis has initiated discussions with various third parties to secure funding for all or some of the Company's innovative pipeline of early stage compounds.

Pharmaxis CEO Mr Gary Phillips said, "The strategies and actions announced today are aimed at mitigating some of the risks associated with drug development in the short term and increasing the opportunity for long term returns. We have some valuable product opportunities at all stages of development and are restructuring the company to take full advantage of that potential in a manner that conserves cash and puts us in a stronger position to navigate the road ahead.

"These decisions have been made in response to recent regulatory and clinical trial setbacks. All areas of the business have been reviewed and we have made some clear strategic choices on how we will do business in the future."

Details of the measures to be undertaken are:

1. **Partnering Bronchitol in CF for the USA**

The agreement with the FDA announced on 22 May 2013 on the development path for Bronchitol in the USA for CF provides a very clear way forward for this opportunity.

Pharmaxis estimates that the revenue potential for Bronchitol in CF with an adult's only indication is in the order of \$160m per annum. The cost of the required Phase 3 clinical trial is estimated at less than \$15m and the product's orphan status guarantees that a successful outcome will give seven years of market exclusivity.

Pharmaxis has already commenced a process to seek a commercial partner to undertake the remainder of the clinical development program and commercialisation of Bronchitol in the USA. Mr Phillips commented, "Now that the pathway to approval for Bronchitol in CF is defined, we believe that it represents an attractive opportunity for other companies with an interest in CF. The additional US\$20m available from the NovaQuest Financing Agreement provides us with viable strategic options to partner Bronchitol at a time when we believe the value to Pharmaxis shareholders will be highest; before, during or after the final Phase 3 study."

2. **Retaining and growing direct commercial interest in Bronchitol for CF markets outside the United States**

Whilst sales have been slower than expected in approved markets, agreement with the UK National Institute for Health and Clinical Excellence, ongoing discussions with the Australian PBAC together with access to new markets through distributors in South America and Eastern Europe is expected to provide sustainable growth in the months and years ahead. Pharmaxis will focus on building these markets and will also seek to leverage its sales and marketing infrastructure in the EU and Australian markets with commercialisation deals for CF products that are complementary to Bronchitol.

3. **Partnering Bronchitol in bronchiectasis**

The recently announced non-significant result in the primary endpoint of the Phase 3 clinical trial in bronchiectasis (B305) means that it cannot be used as the basis for an immediate regulatory application. However, bronchiectasis remains an attractive global market for pharmaceutical companies with an interest in respiratory disease and Bronchitol, with its US orphan status, is an opportunity to be first to market despite the need for further clinical development.

Mr Phillips commented, "Despite the failed primary endpoint there were several important secondary endpoints that did reach statistical significance. The statistically significant improvements in time to first exacerbation, reduction in antibiotic usage and improvement in quality of life are endpoints which we know are seen as valuable to regulatory authorities. All of these endpoints also have a positive impact on health economics and therefore pricing. Our analysis of the extensive database is ongoing, in particular in relation to identifying subgroups that may demonstrate increased responsiveness."

Pharmaxis has commenced a process to partner Bronchitol for bronchiectasis and in the meantime discussions will be held with regulatory authorities to determine the most appropriate clinical trial path based on the B305 analyses.

4. **Securing funding for an innovative pipeline of early stage compounds**

Pharmaxis has made good progress both in advancing the evidence base for our two preclinical assets (SSAO and LOXL2 inhibitors) and initiating discussions with a number of commercial and not-for-profit organisations to secure funding from January 2014 onwards. Mr Phillips said, "I am encouraged by early expressions of interest in our pipeline assets. Our aim is to retain a strategic interest but at the same time share the risk involved and leverage the investments made to date."

5. **Restructuring Pharmaxis capabilities**

Pharmaxis has substantially phased out all costs associated with its US commercial, clinical and regulatory capability and will further downsize manufacturing (Australia) and clinical (EU and Australia) capabilities in line with the new business focus.

The impact of the restructuring of the business is set out below:

- Expense reductions totalling \$12 million per annum. In relation to last quarter's annualised run rate (March 2013), these reductions represent 27% of total cash expenditure and 38% of the loss before non-cash charges
- Headcount reduction of 30%
- Approximately 75% of the expense reduction will take effect by the end of third quarter of CY 2013

Pharmaxis will continue to invest long term in:

- CF commercialisation teams in Australia and the EU
- Regulatory teams to support the extension of Bronchitol approvals to new territories
- Clinical management of the soon to commence EU paediatric study - CF204
- Manufacturing capability for Bronchitol and Aridol

In the short term, Pharmaxis will continue to invest in:

- Completing the analysis and close out of the clinical study B305

- Consolidating production into one facility (at 20 Rodborough Road, Frenchs Forest)
- Marketing and contracting activities associated with the various partnering initiatives

Cash at the end of April 2013 was \$70.5m and a further US\$20 million is available under the NovaQuest Financing Agreement upon commencement of the US CF clinical trial.

Mr Phillips said, "Our resources are now focused on short to medium term value generation. The balance of growth strategies and restructuring initiatives outlined today provides a sustainable business platform and the opportunity to capture significant upside as our portfolio of products matures."

Pharmaxis Chairman, Mr Malcolm McComas concluded, "This plan to reshape Pharmaxis gives the company an affordable business model that can be funded out of existing cash resources, emerging revenues from approved products, our agreement with NovaQuest and a potential to share the development costs for both Bronchitol in the United States and our early stage assets. We have made 2013 a year of restructure, in direct response to our failure to achieve regulatory milestones. All areas of our activities have been reviewed and some hard decisions have been made. I believe we have a clear plan and a viable way forward."

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About Pharmaxis

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialization of therapeutic products for chronic respiratory disorders. Its product Aridol® for the assessment of asthma is sold in key international markets. Its product Bronchitol® for cystic fibrosis is launched in Europe and Australia and its development pipeline of products includes Bronchitol for bronchiectasis, ASM8 for asthma and preclinical assets in inflammatory and fibrotic diseases. Pharmaxis is listed on the Australian Securities Exchange (symbol PXS). The company's head office and manufacturing facilities are located in Sydney. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Investor Relations on phone +61 2 9454 7200.

Forward-Looking Statements

Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential for Bronchitol. All forward-looking statements included in this media release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. We cannot guarantee that any product candidate will receive regulatory approval or that we will seek any such approval.