

# **ASX/PXS Media Release**

12 March 2013

#### PHARMAXIS APPOINTS GARY PHILLIPS AS NEW CHIEF EXECUTIVE OFFICER

The Pharmaxis Board has today appointed Mr Gary Phillips to the position of Chief Executive Officer with immediate effect. Mr Phillips has served as the Company's Chief Operating Officer for 5 years having started with Pharmaxis when it listed on the Australian Securities Exchange in 2003.

Dr Alan Robertson steps down and will leave the Company after 13 years of service as the founding Chief Executive Officer. He has agreed to assist Pharmaxis in a consulting capacity to help the Company generate value from its pipeline of early stage assets.

Mr Malcolm McComas, Pharmaxis Chairman said: "Pharmaxis is facing likely delays in the commercialisation of Bronchitol in the United States. Gary Phillips will review the current business model and implement a number of changes aimed at securing Pharmaxis' position as a commercially successful pharmaceutical company and maximising shareholder value. Gary has more than 30 years experience in the pharmaceutical sector and was previously a CEO of Novartis group companies in Europe, Asia and Australia. He has an exceptional knowledge of all aspects of the Pharmaxis business worldwide and a strong relationship with all of our major stakeholders."

"We thank Alan Robertson for his contribution to Pharmaxis since its inception as a venture capital funded start-up. He has created a substantial business and has led the development of a much needed, novel treatment for cystic fibrosis (CF). The Board acknowledges his vision and tenacity in steering Bronchitol and Aridol through complex clinical trials, regulatory approvals and reimbursement processes in global markets."

Dr Alan Robertson said: "The Company is on a solid footing with a strong cash position and with both Aridol and Bronchitol approved in many countries and generating revenue. The path to regulatory approval for Bronchitol in the US is still to be resolved; however, I remain optimistic that a satisfactory outcome will be reached. I look forward to the continued success of the Company and to turning my attention to new challenges and horizons, especially providing advice and support in development of the potential new drugs in the Pharmaxis pipeline."

Mr Phillips said: "We have overcome a number of hurdles to bring Bronchitol to cystic fibrosis patients in Europe and Australia and recently secured additional funding through a financing agreement with NovaQuest. It is vital that we now focus our resources on maximising the growth of Bronchitol's sales while at the same time accelerating the addition of new territories."

Mr Phillips outlined some of the key initiatives to be undertaken in the near future:

# •US Food and Drug Administration (FDA) response

The Company is expecting to receive a response from the FDA next week concerning its application for marketing approval for Bronchitol in cystic fibrosis patients aged 6 and above. Pharmaxis anticipates it will need to request a meeting with the FDA in the second quarter of calendar 2013 to clarify any additional requirements the FDA may have. The Company remains committed to making Bronchitol available to the world's largest CF market. A clear analysis of the

cost and likely timing of fulfilling any FDA requirements is fundamental to the Company's review of its business model.

#### Bronchiectasis

Bronchitol remains the only airway clearance product worldwide in phase 3 clinical trials for bronchiectasis. There are no products currently approved for this serious respiratory disease affecting many hundreds of thousands of people. The Company's current trial (B305) is the largest and longest study ever conducted in bronchiectasis, and reached a major milestone last week when the last patient in the study had their last clinic visit. The primary endpoint of the study is a reduction in exacerbations. The data from the study will soon be collated and analysed. Pharmaxis expects to report the top line results in the second quarter of calendar 2013. The result from B305 will have significant implications for Bronchitol - potentially providing access to significant markets. The outcome is therefore central to the Company's review of its business model.

# •Sales growth of Bronchitol in Europe

Pharmaxis is approaching a 10% market share of adult patients in Germany and continues to make steady progress month by month. The Company is learning more about how the product is being used and has a number of initiatives planned for the months ahead to improve growth rate and patient adherence. Clearing reimbursement hurdles in the remaining EU countries is a challenge given the current economic climate and fast changing regulations. Pharmaxis has however succeeded in England which perhaps has the most rigorous process and is pushing as fast as possible into other EU markets.

## •Sales growth of Bronchitol in Australia

Restrictive entry criteria for reimbursement has led to a slower than expected uptake of new patients. The Company is continuing to work with the Australian government to refine the wording of these restrictions.

### •Expand territories for Bronchitol

The Company aims to leverage the approvals it has in Europe and Australia to enter new markets in Eastern Europe, the Middle East and South America. Progress in this regard will be reported in the second quarter of calendar 2013.

# •Changes to the Company's business model

The outcome of the likely meeting with the FDA regarding Bronchitol and the outcome of the B305 trial are key to determining any necessary changes to the Company's business model. There will be clarity around both issues in the second quarter of calendar 2013 and more specific guidance on the changes will be provided at that point.

## •Generating value from the Company's pipeline of early stage assets

The Company has a number of new projects in various stages of development. In the coming six months, the Company will be assessing a range of options to fund some or all of these programs through to clinical trials. Assets that fall into this category are:

- ➤ Oligonucleotide portfolio including ASM8 which is in phase 2 clinical development for moderate and severe asthma, and PXS1100 and PXS2200 which are for COPD and asthma respectively, and are both at a preclinical stage.
- ➤ Orbital a new respiratory device which is uniquely capable of delivering respiratory drugs that require a high dose (such as mannitol and antibiotics) without the need for multiple doses.

- > PXS4728 an SSAO inhibitor that is in preclinical development as an anti inflammatory/anti fibrotic once a day oral drug for several indications.
- ➤ LOX / LOXL2 Inhibitor Program a small molecule active against a well known target important in several fibrotic diseases and some cancers.
- ➤ PXS64/PXS25 an anti-fibrotic drug that has completed its preclinical development inhibits the function of TGFb and is targeting the treatment of lung fibrosis.

Mr Phillips concluded: "I look forward to reporting on the outcomes of discussions with the FDA and the results from the bronchiectasis trial in coming months. Further updates on the initiatives outlined above will be provided as matters progress. I am confident that we have both the team and resources to successfully navigate the challenges facing the Company."

Mr Philips has been appointed to the Pharmaxis Board of Directors effective today. The Company is in the process of finalising details of his appointment terms which will be disclosed to the market when concluded.

#### #ends#

**SOURCE:** Pharmaxis Ltd, Sydney, Australia

CONTACT: Felicity Moffatt, phone +61 418 677 701 or email felicity.moffatt@pharmaxis.com.au

#### **About Pharmaxis**

Pharmaxis Ltd (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 recently launched in Europe and Australia and its development pipeline of products includes, Bronchitol for bronchiectasis, PXS64 for the treatment of lung fibrosis, ASM8 for asthma and PXS4728 for fibrotic disease. 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 Aridol and/or 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 can not guarantee that any product candidate will receive regulatory approval or that we will seek any such approval. Factors that could cause or contribute to such differences include, but are not limited to, factors discussed in the "Risk Factors" section of our Statutory Annual Report available on the Pharmaxis website.