

# ASX/NASDAQ Media Release

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## BRONCHITOL PHASE 3 CYSTIC FIBROSIS TRIAL COMPLETES RECRUITMENT

Pharmaxis (ASX:PXS, NASDAQ:PXSL) today announced that the first pivotal Phase 3 clinical trial of Bronchitol for the treatment of cystic fibrosis has completed enrolment.

The first efficacy data from the trial is expected to be available during the first half of 2009. The trial commenced its dosing phase in April 2007, reached its initial recruitment target of 250 subjects in June 2008 and closed today with 325 subjects enrolled. Recruitment was extended to cater for a lower numbers of patients than anticipated entering the study on rhDNASE.

The trial is a double blind, comparator controlled, randomised study comparing 400 mg of Bronchitol twice a day to control. The trial includes a 26-week efficacy and safety component, followed by a 26 week open-label Bronchitol safety extension.

The primary efficacy end-point is change from baseline in FEV1 (forced expiratory volume in one second) after 26 weeks.

Pharmaxis Chief Executive Officer Alan Robertson said: "It is rewarding to reach this milestone in bringing Bronchitol to the marketplace. The study has enrolled well, and we look forward to the results helping to shape cystic fibrosis clinical practice in the future."

Pharmaxis has received Orphan Drug Designation and fast track status from the U.S. Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency for Bronchitol in cystic fibrosis.

Bronchitol is designed to hydrate the airway surface of the lungs, improve lung hygiene and promote normal lung clearance.

Approximately 75,000 people in the major pharmaceutical markets are affected with cystic fibrosis and no products have been approved to improve lung hydration.

To find out more about Pharmaxis, go to <a href="http://www.pharmaxis.com.au">http://www.pharmaxis.com.au</a>.

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#### **About Bronchitol**

Pharmaxis Ltd is developing Bronchitol for the management of chronic obstructive lung diseases including bronchiectasis, cystic fibrosis and chronic bronchitis. Bronchitol is a proprietary formulation of mannitol administered as a dry powder in a convenient hand-held inhaler. It is designed to hydrate the lungs, restore normal lung clearance mechanisms, and help patients clear mucus more effectively. Clinical studies have shown Bronchitol to be well tolerated, to improve quality of life, and to stimulate mucus hydration and clearance in people with bronchiectasis and cystic fibrosis.

### **About Pharmaxis**

Pharmaxis (ACN 082 811 630) is a specialist pharmaceutical company involved in the research, development and commercialization of therapeutic products for chronic and acute respiratory diseases. Our pipeline of products includes Aridol for the management of asthma, Bronchitol for cystic fibrosis, bronchiectasis and chronic obstructive pulmonary disease (COPD), PXS25 for the treatment of interstitial lung disease and PXS4159 for asthma.

Founded in 1998, Pharmaxis is listed on the Australian Stock Exchange (symbol PXS), and on NASDAQ Global Market (symbol PXSL). The company is headquartered in Sydney at its TGA-approved manufacturing facilities. For more information about Pharmaxis, go to www.pharmaxis.com.au or contact Investor Relations +61 2 9454 7200.

## **Forward-Looking Statements**

The statements contained in this media release that are not purely historical are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. 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 cannot guarantee that any product candidate will receive FDA or other 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 and Other Uncertainties" section of our Form 20-F lodged with the U.S. Securities and Exchange Commission.