

23<sup>rd</sup> September 2008



## **Company Announcement**

### **Phosphagenics Announces Initiation of Phase 1 Clinical Trial in Humans for its Transdermal Lidocaine**

Phosphagenics Limited (“Phosphagenics”) (ASX: POH; AIM: PSG; OTCQX: PPGNY) announced today that it has initiated a phase 1 human clinical trial using its patented drug delivery system, TPM, for the targeted delivery of a leading pain relief drug, lidocaine. The trial will compare the dermal bioavailability and will measure the systemic exposure of lidocaine in one of the leading marketed products, Xylocaine<sup>®</sup> (5% lidocaine), and Phosphagenics’ lidocaine (5% lidocaine).

Earlier this year, the Company’s pre-clinical results demonstrated that through the utilisation of Phosphagenics’ patented lidocaine formulation, skin concentration of lidocaine was approximately 900% higher 5 hours after topical application as compared to Xylocaine<sup>®</sup>. In addition, Phosphagenics’ lidocaine was able to significantly increase the depth of lidocaine penetration by approximately 500% in the thigh muscle of animals treated compared to Xylocaine<sup>®</sup>.

Dr Esra Ogru, Executive Vice President of Research and Development at Phosphagenics, said; “Lidocaine is a well known topical anaesthetic used for a wide variety of ailments, including temporary relief of rashes, stings, sprains, strains, bites, and burns. However it has poor penetration into the dermis, frequently rendering it largely ineffective.”

“Our pre-clinical study showed that Phosphagenics’ lidocaine formulation has the potential to provide patients with rapid pain relief, while not increasing systemic exposure, and we are excited to continue moving this program forward efficiently,” she said.

This most recent trial is being conducted at the Centre for Pharmaceutical Research, University of South Australia, under the guidance of Dr. David Foster, as the Principal Investigator. It is an open label, single centre bioavailability trial of dermal and systemic pharmacokinetics in 12 healthy adult volunteers incorporating secondary endpoints of safety and tolerability. The Company expects to report results of the phase 1 trial in the first quarter of 2009.

Harry Rosen, President and CEO at Phosphagenics said; “We believe we have a very attractive commercial product that has shown the potential to substantially enhance the current standard of care.”

**Ends...**

## **APPENDIX AND NOTES TO EDITORS**

### **About Phosphagenics Limited**

Phosphagenics is a Melbourne-based, globally driven biotechnology company focused on the discovery of new and cost effective ways to enhance the bioavailability, activity, safety and delivery of proven pharmaceutical and nutraceutical products.

Phosphagenics' core technology is built around the science and application of phosphorylation, a process where the addition of a phosphate group has been found to enhance the bioavailability, activity and safety of existing pharmaceuticals and nutraceuticals, as well as to assist in the production of drug delivery platforms.

Phosphagenics' shares are listed on the Australian Stock Exchange (POH) and the London Stock Exchange's Alternative Investment Market (PSG). An ADR – Level 1 program was established in the U.S. with The Bank of New York Mellon (PPGNY) for U.S. investors to trade in Phosphagenics' stock on the 'over-the-counter' market. In July 2007, this was upgraded to the International OTCQX, a new premium market tier in the U.S. for international exchange-listed companies, operated by Pink Sheets, LLC.

For more information, please visit Phosphagenics' web site at [www.phosphagenics.com](http://www.phosphagenics.com)

### **Safe Harbor Statement**

This press release contains forward-looking statements based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialise, actual results could vary materially from the Phosphagenics' expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations.

### **Company Contact Details:**

Dr. Esra Ogru  
Phosphagenics Limited  
Executive VP R&D  
+61 3 9605 5900

Mary McSwiggan  
Phosphagenics Limited  
Investor Relations Manager  
+61 3 9605 5907

### **U.S. Investor and Media Contacts:**

Brian Ritchie  
FD  
+1 212 850 5683