



ASX Announcement

ASX code: MBP

## Metabolic discontinues clinical trial programme for neuropathic pain drug, ACV1

**Melbourne. 14 August 2007. Metabolic Pharmaceuticals Limited (“Metabolic”)** advises that it does not intend at the present time to continue the development of ACV1 as a compound to treat neuropathic pain.

Despite the Phase 2A trial of ACV1 in sciatic neuropathic pain having been recently completed, the results of that trial (which are yet to be fully analysed) have been overshadowed by the results of contemporaneous *in vitro* studies on the ability of ACV1 to block the human  $\alpha 9\alpha 10$  nicotinic acetylcholine receptor (nAChR), the probable target of ACV1.

This second study, which was commenced shortly after the  $\alpha 9\alpha 10$  nAChR was identified as the probable molecular target for ACV1 in rats, was undertaken to accurately inform dose selection in future clinical trials. While there is normally similar activity of drug candidates across human and rodent receptors, the study results showed that ACV1 is dramatically less able to block the human  $\alpha 9\alpha 10$  nAChR than it is to block the equivalent rat receptors.

### **What this means for the ACV1 pain programme**

This lower ability of ACV1 to block the human  $\alpha 9\alpha 10$  nAChR means that much larger doses of ACV1 than the dose used in the recently completed Phase 2A trial would be necessary to see effects in humans. Doses at the required level are unlikely to be feasible (impractical to inject and cost of goods prohibitive). The Company has therefore concluded that the ACV1 clinical programme is no longer tenable. As a consequence of that decision, the ongoing Phase 2A trial of ACV1 in diabetic neuropathic pain and post-herpetic neuralgia (shingles related pain) will also be stopped.

No further ACV1 trials are foreseen.

### **What this means for Metabolic**

With the closure of the ACV1 project, the focus of the Company's research and development will be the *Oral Peptide Delivery Platform*. Encouraging progress has been made on this project in recent months.

The objective of Metabolic's proprietary platform is to create new versions of injected peptide drugs that can be taken orally (swallowed). In rodent studies, this platform technology has now been used to orally deliver a number of previously injected peptide drugs. All internal research efforts will now focus on the oral delivery of certain high value peptide drugs (for example, insulin) and further development of the platform for broader application. The research activities around this platform will now be accelerated and expanded.

The Board believes that this platform technology has significant potential value. It should be pointed out, however, that the *Oral Peptide Delivery Platform* remains a research project at the preclinical stage and no drug candidates are expected to be ready for clinical trials for at least 18 months. In the Board's view it

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would be desirable to balance this activity with the in-license of one or more clinical stage projects if appropriate projects can be identified.

Outside of the development of the *Oral Peptide Delivery Platform* technology, the Company's activities will primarily be:

- Completion of the present research activities around the use of *AOD9604* as an osteoporosis drug. On finalisation of this work, the Company will seek to out-license further development of the drug. The Company does not intend to continue development itself; and
- Seeking new opportunities to in-license one or more clinical stage projects.

Metabolic has approximately \$18 million in cash reserves. With the cessation of the Company's clinical trial programme for *ACV1*, the Company has sufficient cash resources to fund development of the *Oral Peptide Delivery Platform* through the next stage.

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**About Metabolic**

Metabolic Pharmaceuticals Limited (**ASX: MBP, NASDAQ OTC: MBLPY**) is a Melbourne based, ASX listed biotechnology company with 300 million shares on issue. Metabolic's main focus is to take innovative drugs, with large market potential, through formal preclinical and clinical development. The Company is primarily developing a platform for the oral delivery of existing injected peptide drugs. This platform has potential for use by other companies developing peptide drugs. For more information please visit the Company's website at [www.metabolic.com.au](http://www.metabolic.com.au).

**Inherent Risks of Investment in Biotechnology Companies**

There are many inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology. Companies such as Metabolic are dependent on the success of their research projects and on the ability to attract funding to support these activities. Investment in research and development projects cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Thus investment in companies specialising in these, such as Metabolic, must be regarded as highly speculative. Metabolic strongly recommends that professional investment advice be sought prior to such investments.

**Forward-looking statement**

Certain statements in this ASX Announcement may contain forward-looking statements regarding the Company's business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing the Company's goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavor of building a business around such products and services. Metabolic undertakes no obligation to publicly update any forward looking statement, whether as a result of new information, future events, or otherwise. Actual results could differ materially from those discussed in this update. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the Metabolic Pharmaceuticals Limited Annual Report for the year ended June 30, 2006, copies of which are available from the Company or at [www.metabolic.com.au](http://www.metabolic.com.au).