



ASX Announcement (305)  
12 September 2008

### **Virax Co-X-Gene™ Technology Licence with Transgene Update on Clinical Development Plan for TG4001 in Cervical Cancer**

Virax Holdings Limited (ASX:VHL) advises that Transgene and Roche have announced an extension to the clinical development plan for Transgene's product TG4001/R3484, the human papilloma virus (HPV) targeted therapeutic vaccine for the treatment of pre-cancerous lesions of the cervix.

TG4001/R3484 was developed by Transgene using Virax's Co-X-Gene™ technology. Virax is entitled to royalty and milestone payments under a Licence Agreement with Transgene, who subsequently licensed the product to the pharmaceutical company Roche for treatment of HPV related pathologies. Roche has exclusive worldwide marketing rights for TG4001/R3484 and is funding all costs associated with the development of the vaccine and is leading clinical studies.

Transgene and Roche have advised of their decision to modify the trial program by initiating a further Phase II study of the therapeutic vaccine. The purpose of the trial is to provide valuable additional clinical data to optimise the profile definition of the product and allow for the study of new treatment modalities. This approach is expected to significantly increase the prospects of the product's future success. The trial will be conducted prior to the Phase III trial previously scheduled for the final quarter of 2008. Regulatory clearance for the conduct of the Phase III trial was announced in June 2007.

Virax's Chief Executive Officer, Larry Ward stated, "The decision to extend the trial program is in everybody's long term interests. By reducing the risk of the program the overall value of the product is enhanced and the likelihood of eventual success in the pivotal phase III studies is increased. I remain convinced that the combination of Roche's excellence in clinical development of oncology products and Transgene's undoubted expertise in the utilization of live viral vectors as therapeutic vaccines means that TG4001/R3484's development is in very safe hands."

Virax has previously announced a strategy of seeking a corporate transaction with another vaccine or related technology company so as to broaden its development program pipeline with respect to risk and reward. In addition it has taken a variety of cost-cutting measures so as to facilitate ongoing operations, protection of the Transgene sub-license and progression of the South African trial of VIR201 using non-dilutive external funding. Commenting on the ongoing strategic direction of the Company Larry Ward said, "The extension of the TG4001/R3484 trial program will delay the timing of the launch of the product onto the market and therefore has consequences for the timing of potential milestone and royalty payments to Virax. The Board which is actively considering various options will take the development status of the Transgene products into account when evaluating such options and

progressing any recommendations in relation to corporate transactions or any future fundraisings. This recent announcement with respect to TG4001/R3484 will no doubt only give added momentum to the decision making progress. We are conscious of the need to keep stakeholders informed of progress in relation to the strategy and are committed to providing a further update prior to this year's AGM to be held by 30 November 2008."

### **About Virax**

Virax, based in Melbourne, Australia, is a biopharmaceutical company engaged in the discovery and development of novel immunotherapeutic products for the treatment of chronic infectious diseases and cancer. The Company's lead product, VIR201, an HIV/AIDS immunotherapeutic (therapeutic vaccine), has been tested successfully in two clinical trials in Australia. Regulatory clearance has been received from both the US FDA to perform Phase II testing and from the South African regulatory authority (MCC) to conduct a Phase I/IIa trial of VIR201. Funding for the Southern African trial is non-dilutive to Virax and has been contributed by a consortium of global and Southern African resource companies led by BHP Billiton. Preparatory work is now being finalised for the commencement of the Southern African trial.

Transgene (Eurolist Paris: FR0005175080) has a License Agreement with Virax for access to Co-X-Gene™ technology for use in two of Transgene's immunotherapeutic products. These are TG4001 - a treatment for pathologies relating to human papilloma virus (HPV) infection that can lead to cervical cancer - and TG4010 - a treatment for non-small cell lung cancer (NSCLC). This was reported to the ASX in the Company's announcement of 13 March 2007 and is referred to as the "Transgene Sub-licence". TG4001 is in advanced development with one completed Phase II showing promising safety and efficacy. An additional Phase II trial is planned so as to optimise the product profile. Transgene has licensed TG4001 to the pharmaceutical company Roche for treatment of HPV related pathologies. Phase IIb testing of TG4010 in NSCLC is currently underway with successful interim data being achieved. Transgene reported that the data warranted further development of TG4010 in Phase III trials and that it has initiated discussions with potential partners to complete the last stages of clinical development and bring TG4010 to the market. The Company would benefit from any payments to Transgene upon completion of such an agreement.

Additional information about Virax is available at [www.virax.com.au](http://www.virax.com.au)

For further information contact:

Dr Larry Ward  
CEO, Virax Holdings Limited  
Melbourne, Australia  
(03) 9854 6230

Mr John Morrison  
Company Secretary, Virax Holdings Limited  
Melbourne, Australia  
(03) 9854 6230

### **Media**

Ms Nerida Mossop  
Hinton & Associates  
Melbourne, Australia  
(03)96001979  
0437 361 433