



*(Incorporated in the Cayman Islands with Limited Liability)*

Stock Code: 0575

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## ANNOUNCEMENT



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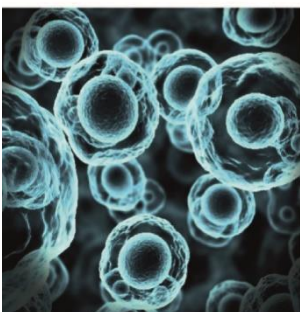
### OPERATIONS UPDATE – FORTACIN™

The directors (the “**Directors**” or the “**Board**”) of Regent Pacific Group Limited (the “**Company**” and collectively with its subsidiaries, the “**Group**”) wish to inform the shareholders of the Company and potential investors of the following updates in respect of its operations in relation to Fortacin™.

The below operations update is a follow on from the Group’s last operations update announcement of 18 June 2020 and should be read in conjunction with that update.

### US Approval and Commercialisation Progress

Further to our last operations update of 18 June 2020, the Group has continued to make steady progression with the approval process with the United States (the “**US**”) Food and Drug Administration (“**FDA**”) with regards to its Phase II validation study of Fortacin™. In this respect, as of 3 August 2020, 108 subjects have been screened (with 37 subjects having failed Visit 1), 108 subjects received a diary, 69 subjects randomised at visit 2 (with 20 subjects having failed visit 2) and 54 subjects completed (being visit 3). The Group’s target is to enrol a further 22 subjects by end of September 2020 with the aim of randomising 33 additional and completed subjects by end of October 2020, bringing the total to the study’s target of approximately 101 randomised and completed subjects for the Phase II validation study.



The slight delay is due to COVID-19 surging again in our high enrolling sites in Florida and Georgia and the hurricane Isaias that recently went through Florida. However, if the site centres are successful in completing the randomisation, as mentioned, the Group remains on target to complete the Phase II validation study of Fortacin™ by the end of 2020. However, any delay in recruiting and randomising the required subjects, whether as a result of COVID-19 or other reasons, would delay the completion of the study. On the assumption that the trial is sufficient to convince the US FDA that the Premature Ejaculation Bothersome Evaluation Questionnaire (PEBEQ) serves as an appropriate measure for support of a label claim, the pivotal Phase III study could commence in the latter half of 2020, with New Drug Application (“**NDA**”) submission possible in the first half of 2021, giving a Prescription Drug User Fee Act (PDUFA) date in Q1 2023. These dates remain as stated in the Company’s Annual Report for 2019 and our recently announced annual results announcement dated 31 March 2020. Despite the difficulties presented by COVID-19, particularly as it relates to securing face-to-face meetings, the Group’s strategy remains to continue negotiations with potential commercial strategic partners for the US market while we undertake the clinical work with the aim of securing a partner just ahead of or while we conduct the Phase III trial.

Formal registration of the Phase II validation study of Fortacin™ in the US remains a critical and positive step towards making the NDA submission and ultimately achieving all necessary FDA and other US regulatory approvals needed to commercialise Fortacin™ in the US, its most significant potential market.

### **Chinese Approval and Commercialisation Progress**

As mentioned in our last announcement of 18 June 2020, the Group is continuing to progress regulatory approval with Wanbang Pharmaceutical Marketing and Distribution Co., Ltd. (“**Wanbang Pharmaceutical**”), its commercial strategic partner for China. In this respect, Siegfried Evionnaz SA (“**Siegfried**”), the manufacturer of prilocaine, one of the active pharmaceutical ingredients (“**API(s)**”) of Fortacin™, has completed its technical work (being the API structural identification and chemical characterization together with the M7 genotoxic assessment) required for submitting its drug master file (“**DMF(s)**”) to the National Medical Products Administration (“**NMPA**”) in China. Siegfried has now completed the translation of the file into Chinese and is now finishing the redaction of the DMF. Once this is completed, the entire submission will be subject to a final review to ensure all information is included so as to avoid any deficiency letter from NMPA. The aim remains to complete the submission with the NMPA in mid-August 2020, which, as previously mentioned, is a month behind schedule due to work issues it has faced as a result of COVID-19 as Siegfried’s manufacturing site in Switzerland is hampered by off-site working.

However, despite this slight delay we understand that Wanbang Pharmaceutical remains on course for submitting the investigational new drug (“**IND**”) application for clinical trial approval (“**CTA**”) by the end of Q3 2020 as it has already completed the application and is just waiting for Siegfried to file its DMF as that will then trigger and allow Wanbang Pharmaceutical to file the CTA (as its requires the DMF file number for prilocaine) to commence clinical trials in China. On the assumption that the IND can be filed per this timeframe, the CTA could be obtained between Q4 2020 and Q1 2021. As per the terms of the licence agreement executed with Wanbang Pharmaceutical, and announced on 3 December 2018, a payment of US\$4 million (or approximately HK\$31.20 million) is payable to the Group upon obtaining Chinese regulatory approval to conduct a human clinical trial of a licensed product.

### **Progress Relating to Change of Status of Fortacin™ to OTC from Rx**

Recordati S.p.A. (“**Recordati**”) has informed the Company that it has received a positive opinion from Committee for Medicinal Products for Human Use (CHMP) on 23 July 2020 for switching Fortacin™ to “Over-the-Counter” (“**OTC**”) status from prescription (“**Rx**”), with the European Commission Decision expected on or around 23 September 2020. The OTC switch is a move designed to significantly increase sales and consequently uplift the royalty payments to the Group. If this approval process is achieved, Recordati has mentioned that it would look to start the OTC launch from January 2021, provided that Pharmaserve (North West) Limited (“**PSNW**”), the manufacturer, can meet the anticipated increased demand and that COVID-19 does not further complicate or impede the planned launch.

Recordati, PSNW and the Group are looking into options at scaling up the manufacturing process to meet the anticipated demand in OTC with the aim of manufacturing approximately 50,000 units per batch order and reducing the risk of supply chain shortage and unreliability.

### **Taiwanese, Hong Kong and Macau Approval and Commercialisation Progress**

There is no further progress to update on the Taiwanese, Hong Kong and Macau approval and commercialisation progress since our last update of 18 June 2020. For ease of reference, an extract is provided below of that update.

Orient EuroPharma Co., Ltd. (“**Orient EuroPharma**”), the Group’s commercial strategic partner for Taiwan, Hong Kong, Macau and certain other countries in South East Asia, has received the first deficiency letter from the Taiwan Food and Drug Administration (“**TFDA**”) in respect of its application for Fortacin™ and it has completed and sent back its response and supporting documents on 16 June 2020. TFDA has recently approved the DMFs for lidocaine and prilocaine, the active pharmaceutical ingredients of Fortacin™. On the assumption that TFDA does not have any further questions / deficiencies, Orient EuroPharma anticipates approval around January

2021, which would trigger a payment of US\$300,000 (or approximately HK\$2.34 million) to the Group.

Further to our annual results announcement of 31 March 2020, we remain hopeful that Orient EuroPharma can launch Fortacin™ in Hong Kong and Macau in 2020, but this is very much dependent on whether COVID-19 further complicates or impedes the planned launch and whether PSNW is able to deliver product to Orient EuroPharma from Recordati's batch orders, as the minimum purchase order is 13,000 units per batch order and Orient EuroPharma requires significantly less than that for its launch.

### **Other Out-Licensing Opportunities**

The Company remains in discussions with our commercial strategic partners for the Middle East, India, North America and Latin America (LATAM) region. However, it is not possible to determine with accuracy the timing of completion of such agreements, and no assurance can be given that negotiations will lead to a binding licencing agreement(s) in the aforementioned jurisdictions or at all.

The Group will continue to work closely and diligently with its current and prospective commercial partners and will keep shareholders and potential investors informed of any new developments of note as and when they occur.

### **COVID-19**

The outbreak of Covid-19 has had, and continues to have, a material impact on businesses around the world and the economic environments in which they operate. The outbreak has caused disruption to across our business lines as highlighted above. A number of countries in which we operate have implemented severe restrictions on the movement of populations, with a resultant significant impact on economic activity. These restrictions are being determined by the governments of individual jurisdictions, including through the implementation of emergency powers. The impacts of these restrictions, including the subsequent lifting of restrictions, may vary from jurisdiction to jurisdiction. We have invoked certain plans at our offices in Hong Kong and the United Kingdom to help ensure the safety and wellbeing of our staff, as well as our ability to support our customers and maintain our business operations. Many of our staff have continued to provide continuity of work while working remotely. It remains unclear how this will evolve through 2020 and into 2021 and we continue to monitor the situation closely.

**Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.**

Note: Unless otherwise specified herein, the amounts dominated into US\$ have been translated, for the purpose of illustration only, into HK\$ using the exchange rate of US\$1.00 = HK\$7.80.

On Behalf of the Board of  
**Regent Pacific Group Limited**

Jamie Gibson  
*Executive Director*

**Directors of the Company:**

James Mellon (*Chairman*)\*  
Jamie Gibson (*Chief Executive Officer*)  
David Comba#  
Julie Oates#  
Mark Searle#  
Jayne Sutcliffe\*

\* *Non-Executive Directors*

# *Independent Non-Executive Directors*

Hong Kong, 5 August 2020