



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

Stock Code: 0575

18 March 2019

## ANNOUNCEMENT



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### SETTLEMENT OF AUSTRALIAN TAXATION DISPUTE AND OPERATIONS UPDATE

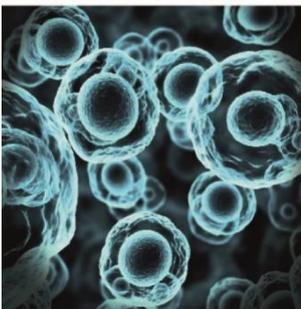


#### SUMMARY

This announcement is made by the Company in compliance with the disclosure requirements under Rule 13.09 of the HK Listing Rules and the Inside Information Provisions (as defined under the HK Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

#### Settlement of Australian Taxation Dispute

The Directors are pleased to announce that, on 18 March 2019, the Company entered into a settlement agreement with the Australian Taxation Office in respect of the Dispute for an amount of AUD 9.5 million (or approximately USD 6.73 million or HKD 52.49 million), payable within 90 days of the date of the settlement agreement. The settlement amount was well below the potential exposure of AUD 19.12 million (or approximately USD 13.55 million or HKD 105.69 million), calculated to include accrued interest as at 1 March 2019, and has facilitated the discontinuance of the litigation.



## Operations Update

The Company has further progressed the approval process with the FDA in the US. In this respect the Phase II validation study of Fortacin™ in respect of the FDA approval process was officially registered on 6 July 2018, with patients being enrolled into the study from December 2018. Currently, there are 12 test centres open for recruitment of patients in the US, with eight more test centres to be opened to facilitate recruitment. The phase II clinical trial is estimated to complete by Q1 2020. On the assumption that the trial is sufficient to convince the FDA that the PEBEQ serves as an appropriate measure for support of a label claim, pivotal Phase III work could commence in the Q1 2021, with NDA submission possible in Q1 2022, giving a PDUFA date in 2022.

In January 2019, the Company submitted an application to The Hong Kong Department of Health – Drug Office for the transfer of the marketing authorisation to Orient EuroPharma Co. Ltd, which on approval (expected to take between 2 to 3 months from the date of submission) will allow them to distribute and sell Fortacin™ in Hong Kong and Macau, which is expected in 2019.

The Company is progressing its Investigational New Drug submission with the Centre for Drug Evaluation in China with Wanbang Pharmaceutical, with the parties having a team meeting in the United Kingdom this week for the purposes of finalising the protocol around the submission, which is anticipated to be made in Q3 2019. This submission and approval of the Investigational New Drug would trigger further payments from Wanbang Pharmaceutical to the Group of up to USD 4 million (or approximately HKD 31.20 million).

Recordati has launched Fortacin™ in the United Kingdom in February 2019 and will look to roll out Fortacin™ in its other countries over the next few years.

A more detailed operations update will be provided in the Company's annual report for the financial year ended 31 December 2018 that is due to be dispatched to the Company's shareholders no later than 30 April 2019.

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

This announcement is made by Regent Pacific Group Limited (the “**Company**” and collectively with its subsidiaries, the “**Group**”) in compliance with the disclosure requirements under Rule 13.09 of The Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**HK Listing Rules**”) and the Inside Information Provisions (as defined under the HK Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

### **Settlement of Australian Taxation Dispute**

The directors of the Company (the “**Directors**” or the “**Board**”) refer to the prior disclosures in the Company’s annual and interim reports, together with announcements dated 28 January, 18 April and 23 August 2013 in respect of the Company’s dispute with the Australian Taxation Office in connection with a disposal by the Group of an investment in BC Iron Limited, a company whose securities are listed on the Australian Securities Exchange (the “**Dispute**”). The essence of the Dispute related to whether capital gains tax was payable on the capital gains made by the Company from that disposal. As disclosed, the Australian Taxation Office considered that capital gains tax was payable in the amount of approximately AUD 11.85 million (or approximately USD 8.39 million or HKD 65.44 million) (as amended down by way of an amended assessment on 7 September 2016 so as to include some additional costs associated with the Group’s investment in BC Iron Limited). This excludes interest that had accrued on this amount since 2 December 2013 (which, as at 1 March 2019, was approximately AUD 7.27 million (or approximately USD 5.15 million or HKD 40.17 million)), making the total potential amount payable AUD 19.12 million (or approximately USD 13.55 million or HKD 105.69 million).

As disclosed, a trial date of 18 March 2019 had been set to hear the matter, with the matter set down to be heard over three (3) days in the Australian Federal Court.

The Directors are pleased to announce that, on 18 March 2019, the Company entered into a settlement agreement with the Australian Taxation Office in respect of the Dispute for an amount of AUD 9.5 million (or approximately USD 6.73 million or HKD 52.49 million), payable within 90 days of the date of the settlement agreement. The settlement amount was well below the total potential amount payable to the Australian Taxation Office of AUD 19.12 million (or approximately USD 13.55 million or HKD 105.69 million) and has facilitated the discontinuance of the litigation.

While the expert and independent Australian advice received did not change throughout the Dispute and at no stage did the Directors consider that any tax was payable, as part of the dispute resolution process the Board was compelled to consider the inherent litigation risk associated with pursuing the matter through the Australian courts. Consequently, it was decided that the aforementioned settlement was in the best interests of the Group and its shareholders as a whole.

Having reached the settlement, the Group is now able to divert more resources to our exciting operational matters referred to below.

The impact of the settlement amount of AUD 9.5 million (or approximately USD 6.73 million or HKD 52.49 million) to the Group's financial performance in 2019 will be offset by: (i) any unrealised marked-to-market gains on the securities portfolio which, as at close of market today, stood at USD 2.05 million (or approximately HKD 15.99 million); and (ii) any positive performance of the Group's other assets and investments, including West China Coking and Gas Company Limited. In recognising this, shareholders should note that the listed equity portfolio changes on a daily basis as it is marked-to-market and the contributions from the Group's other assets and investments, if equity accounted, rely on the monthly financial performance of that asset or investment.

### **Operations Update**

The Company has further progressed the approval process with The Food and Drug Administration of the United States (the “**US**”) Department of Health and Human Services (the “**FDA**”). In this respect the Phase II validation study of Fortacin™ in respect of the FDA approval process was officially registered on 6 July 2018, with patients being enrolled into the study from December 2018. Currently, there are 12 test centres open for recruitment of patients in the US, with eight more test centres to be opened for facilitating recruitment. The phase II clinical trial is estimated to complete by Q1 2020. On the assumption that the trial is sufficient to convince the FDA that the Premature Ejaculation Bothersome Evaluation Questionnaire (the “**PEBEQ**”) serves as an appropriate measure for support of a label claim, pivotal Phase III work could commence in the Q1 2021, with New Drug Application (“**NDA**”) submission possible in Q1 2022, giving a Prescription Drug User Fee Act (the “**PDUFA**”) date in 2022. These dates are the most recent guidance received and update all previous estimates on the FDA process set out by the Company in its announcements, annual and interim reports and investor presentations but are ultimately dependent for example on the timing it takes to enrol patients in the trials, the feedback received from the FDA and time to taken to address any issues that have been received from the FDA. Formal commencement of the Phase II validation study of Fortacin™ in the US in December 2018 is 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.

The Company has also made significant and positive progress with the Hong Kong Department of Health – Drug Office and the Macau Government Health Bureau. On 4 November 2018, the Company was advised by its regulatory agent that it had successfully registered Fortacin™ in Hong Kong with The Hong Kong Department of Health – Drug Office. In January 2019, the Company submitted an application to The Hong Kong Department of Health – Drug Office for the

transfer of the marketing authorisation to Orient EuroPharma Co. Ltd, which on approval (expected to take between 2 to 3 months from the date of submission) will allow them to distribute and sell Fortacin™ in Hong Kong and Macau, which is expected in 2019. Registration will run for an initial period of 5 years expiring on 18 October 2023 and thereafter for periods of five years at a time on renewal.

The Company is progressing its Investigational New Drug submission with the Centre for Drug Evaluation in China with Wanbang Pharmaceutical Marketing & Distribution Co., Ltd. (“**Wanbang Pharmaceutical**”), with the parties having a team meeting in the United Kingdom this week for the purposes of finalising the protocol around the submission, which is anticipated to be made in Q3 2019. The submission will include all information from the dossier that was submitted to the European Medicines Agency for obtaining approval, which is in the process of being translated into Chinese by Wanbang Pharmaceutical. This submission and approval of the Investigational New Drug would trigger further payments from Wanbang Pharmaceutical of up to USD 4 million (or approximately HKD 31.20 million).

Recordati has launched Fortacin™ in the United Kingdom in February 2019 and will look to roll out Fortacin™ in Romania and Greece later this year and in its other countries over the next few years.

A more detailed operations update will be provided in the Company’s annual report for the financial year ended 31 December 2018 that is due to be dispatched to the Company’s shareholders no later than 30 April 2019.

**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, (i) amounts dominated in AUD have been translated, for the purpose of illustration only, into USD using the exchange rate of AUD 1.00 = USD0.7085; and (ii) amounts dominated in USD have been translated, for the purpose of illustration only, into HK\$ using the exchange rate of USD1.00 = HKD7.80.

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

Jamie Gibson  
*Director*

**Directors of the Company:**

James Mellon (*Chairman*)<sup>\*</sup>

Jamie Gibson (*Chief Executive Officer*)

David Comba<sup>#</sup>

Julie Oates<sup>#</sup>

Mark Searle<sup>#</sup>

Jayne Sutcliffe<sup>\*</sup>

<sup>\*</sup> *Non-Executive Directors*

<sup>#</sup> *Independent Non-Executive Directors*

Hong Kong, 18 March 2019