



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

Stock Code: 0575

24 October 2017

## ANNOUNCEMENT

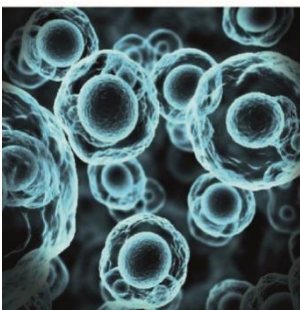
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## OPERATIONS UPDATE

### 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).

The Directors refer to the Company's announcements dated 14 August and 3 October 2017 and are pleased to inform the shareholders of the Company and potential investors that: (i) on 23 October 2017 (after market close), the Group received €4 million (or approximately US\$4.71 million or HK\$36.74 million) from Recordati in respect of the Amended and Restated Licence Agreement becoming effective; (ii) the Group has received the EMA Opinion on 11 October 2017 where the EMA has recommended the transfer of the European Marketing Authorisation of Fortacin™ to Recordati from Solutions; (iii) the Group has recently submitted applications to the Hong Kong Department of Health Drug Office and the Macau Government Health Bureau to acquire import licences to allow for the sale of Fortacin™ in Hong Kong and Macau, the approval processes for which are expected to take between 18 and 24



months, for Hong Kong, and between 6 to 12 months, for Macau; and (iv) following execution of the amended development, manufacturing and supply agreement with PSNW on 3 October 2017 for the development, manufacture and supply of the Fortacin™ product, the manufacture of 3 x process validation batches of the 12 dose product under the 380 litre scale has commenced, in advance of the expected sale and distribution of Fortacin™ in Europe by Recordati in early 2018.

The Directors can confirm that Recordati has placed its initial launch orders with the manufacturer, PSNW, for the launch of Fortacin™ in France, Germany, Italy, Spain and Portugal in March 2018, followed by the launch in Greece, Romania, Czech Republic, Slovak Republic and Poland in the second half of 2018 and in the rest of Europe, Russia, the Commonwealth of Independent States (CIS) and select countries of North Africa in the coming years.

The Company continues to be debt free with approximately US\$13.36 million (or approximately HK\$104.21 million) in cash and listed securities as at the date hereof, being an increase of 198% since 30 June 2017.

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

This announcement is made by the Company in compliance with the disclosure requirements under Rule 13.09 of 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).

Unless the context otherwise requires, capitalised terms used in this announcement shall have the same meaning given to them in the Company's announcement dated 3 October 2017.

### **Milestone Payment Received under Amended and Restated Licence Agreement**

The Directors refer to the Company's announcement dated 14 August and 3 October 2017 and are pleased to inform the shareholders of the Company and potential investors that on 23 October 2017 (after market close), the Group received €4 million (or approximately US\$4.71 million or HK\$36.74 million) in respect of the Amended and Restated Licence Agreement becoming effective. The Group looks forward to receiving further payments in accordance with the milestone and payments schedule outlined in the announcement of 3 October 2017.

## **Transfer of European Marketing Authorisation**

In accordance with the Amended and Restated Licence Agreement, the Company is pleased to announce that the Group's submission for the transfer of the European Marketing Authorisation of Fortacin™ to Recordati from Solutions has been completed pursuant to the European Medicines Agency ("EMA") guidelines. Solutions has now received the EMA Opinion on 11 October 2017 where EMA recommended the transfer of the European Marketing Authorisation of Fortacin™ to Recordati. The final step of the formal transfer of the European Marketing Authorisation is for the European Commission to authorise the transfer, which is expected by the end of December 2017.

## **Marketing Authorisation in Hong Kong and Macau**

The Group has recently submitted applications to the Hong Kong Department of Health Drug Office and the Macau Government Health Bureau to acquire import licences to allow for the sale of Fortacin™ in Hong Kong and Macau. The process for obtaining such marketing authorisation is relatively straight forward and will rely on presentation of the same dossier of information that allowed Fortacin™ to be approved for sale by the EMA. This means that no further clinical trials or supplemental data gathering will be required and approval should be granted on the strength of existing EMA documentation.

The time frame for the Hong Kong Department of Health approval process is expected to be between 18 and 24 months. The Macau Health Bureau approval process is considerably shorter, and is expected to be completed within 6 to 12 months.

## **Manufacturing Update**

The Directors are also pleased to announce that, following execution of the amended development, manufacturing and supply agreement with PSNW for the development, manufacture and supply of the Fortacin™ product for Recordati and Solutions, the manufacture of 3 x process validation batches of the 12 dose product at the 380 litre scale has recently been completed. Stability data on release at time point zero for the first batch has been received with the data being within specification. Activities also remain on track to complete submission to the EMA of a variation application to register the increased batch size in Q1 2018, in advance of the expected sale and distribution of Fortacin™ in Europe by Recordati in early 2018. Recordati is expected to begin sales of Fortacin™ in France, Germany, Italy, Spain and Portugal in early 2018, and in the rest of Europe, Russia, the Commonwealth of Independent States (CIS) and select countries of North Africa in the coming years.

Additional stability data has been generated on the 3 x Good Manufacturing Practice (GMP) batches of the 12 dose product manufactured at PSNW, which were used to support registration of the 12 dose product to the European Marketing Authorisation. Stability data at the 18 month timepoint, which corresponds to the end of the registered shelf life, was within specification for all 3 GMP batches.

### **Commercial launch of Fortacin™ in Europe by Recordati**

The Directors can confirm that Recordati has placed its initial launch orders with the manufacturer, PSNW, for the launch of Fortacin™ in France, Germany, Italy, Spain and Portugal in March 2018, followed by the launch in Greece, Romania, Czech Republic, Slovak Republic and Poland in the second half of 2018 and in the rest of Europe, Russia, the Commonwealth of Independent States (CIS) and select countries of North Africa in the coming years.

### **General**

The Company continues to be debt free with approximately US\$13.36 million (or approximately HK\$104.21 million) in cash and listed securities as at the date hereof, being an increase of 198% since 30 June 2017. The Group will continue to work closely and diligently with its commercial partners and will keep shareholders and potential investors informed of any new developments as and when they occur.

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

Note: Unless otherwise specified herein, amounts denominated in: (i) EUR have been translated, for the purpose of illustration only, into US\$ using the exchange rate of EUR 1.00 = US\$1.1781; and (ii) 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  
*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, 24 October 2017