



**Regent Pacific Group Limited** 8th Floor, Henley Building 5 Queen's Road Central Hong Kong

(Incorporated in the Cayman Islands with Limited Liability)

Stock Code: 0575

3 December 2018

# ANNOUNCEMENT

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# LICENCE AGREEMENT WITH WANBANG PHARMACEUTICAL MARKETING AND DISTRIBUTION CO., LTD. FOR THE COMMERCIAL LAUNCH OF FORTACIN™ IN THE PEOPLE'S REPUBLIC OF CHINA

# HIGHLIGHTS

- Regent Pacific to receive up to US\$13 million in upfront licence payments and upon launch of first commercial sales.
- Regent Pacific to receive up to US\$25 million in sales milestones, together with royalties ranging from low to highteens.
  - Fortacin<sup>™</sup> has the potential to help an initial target market of approximately 9 million patients in China in its first year of launch, rising to over 170 million patients by its tenth year.
- Regent Pacific retains full commercial rights to Fortacin<sup>™</sup> in all unlicensed countries, including the United States.



## 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 are pleased to inform the shareholders of the Company and potential investors that on 3 December 2018 (after market close in Hong Kong) Solutions, an indirect wholly-owned subsidiary of the Company, entered into the Licence Agreement with Wanbang Pharmaceutical, a wholly controlled company of Shanghai Fosun Pharma, in respect of the rights to commercialise Fortacin<sup>™</sup>, Solutions' novel treatment for premature ejaculation, by way of the sale and, among other things, distribution of Fortacin<sup>™</sup> in The People's Republic of China, excluding Taiwan, SAR Hong Kong and SAR Macau.

Solutions continues to retain full commercialisation rights for Fortacin<sup>™</sup> for the rest of the world, including but not limited to the United States and Canada, Latin America, the Asia Pacific region (excluding the Territory), the Middle East and Sub-Saharan Africa.

Wanbang Pharmaceutical shall, at its own expense: (i) have the responsibility for filing applications for, and obtaining and maintaining any and all regulatory approvals required under applicable law to import and commercialise Fortacin<sup>™</sup> in the Territory, in each case in the name of Solutions; and (ii) take all steps necessary to ensure that Solutions is in compliance with all applicable laws and all requirements on Solutions in connection with any regulatory approvals in the name of Solutions.

Solutions shall provide Wanbang Pharmaceutical, at its cost and at its request, with reasonable assistance in: (i) obtaining any approval, consent or clearance necessary to carry out a clinical study sanctioned by an appropriate regulatory body in the Territory; and (ii) preparing and submitting applications for and obtaining regulatory approval for Fortacin<sup>™</sup> in the Territory.

Pursuant to the Licence Agreement, the Group, acting through Solutions, will be eligible to receive payments of up to US\$38 million (or approximately HK\$296.4 million), excluding royalties after hitting certain milestones related to the PRC roll-out.



It is expected to take between 35 months to 60 months from the date of Wanbang Pharmaceutical submitting the documentation for obtaining the import drug licence from NMPA.

The Licence Agreement is for an indefinite period and contains customary provisions in respect of termination. In addition, the Licence Agreement contains various warranties and indemnities as are customary for such an agreement.

Shareholders and investors should read the whole text of this announcement, including the section entitled "Licence Agreement".

The Group will keep Shareholders and investors updated on the progress made by Wanbang Pharmaceutical in respect of the necessary regulatory approvals in the Territory and the likely commercial launch date for the Territory as and when such details become known.

The Company is also pleased to announce that Wanbang Pharmaceutical has on the date hereof (and also after market close in Hong Kong) entered into a manufacturing and supply agreement with PSNW for the manufacture and supply of Fortacin<sup>™</sup> for Wanbang Pharmaceutical.

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).



## LICENCE AGREEMENT

#### Date

3 December 2018

#### **Parties**

Licensee: Wanbang Pharmaceutical Marketing and Distribution Co., Ltd.

Licensor: Plethora Solutions Limited

The Directors are pleased to inform the shareholders of the Company and potential investors that on 3 December 2018 (after market close in Hong Kong) Solutions, an indirect wholly-owned subsidiary of the Company, entered into the Licence Agreement with Wanbang Pharmaceutical, a wholly controlled company of Shanghai Fosun Pharma, in respect of the rights to commercialise Fortacin<sup>™</sup>, Solutions' novel treatment for premature ejaculation, by way of the sale and, among other things, distribution of Fortacin<sup>™</sup> in The People's Republic of China, excluding Taiwan, SAR Hong Kong and SAR Macau.

Solutions continues to retain full commercialisation rights for Fortacin<sup>™</sup> for the rest of the world, including but not limited to the United States and Canada, Latin America, the Asia Pacific region (excluding the Territory), the Middle East and Sub-Saharan Africa.

#### PRC Regulatory Responsibility

Wanbang Pharmaceutical shall, at its own expense: (i) have the responsibility for filing applications for, and obtaining and maintaining any and all regulatory approvals required under applicable law to import and commercialise Fortacin<sup>™</sup> in the Territory, in each case in the name of Solutions; and (ii) take all steps necessary to ensure that Solutions is in compliance with all applicable laws and all requirements on Solutions in connection with any regulatory approvals in the name of Solutions.

Solutions shall provide Wanbang Pharmaceutical, at its cost and at its request, with reasonable assistance in: (i) obtaining any approval, consent or clearance necessary to carry out a clinical study sanctioned by an appropriate regulatory body in the Territory; and (ii) preparing and submitting applications for and obtaining regulatory approval for Fortacin<sup>™</sup> in the Territory.

When it becomes feasible under applicable law and at the written request of Wanbang Pharmaceutical, Solutions shall transfer the import authorisation, once obtained, to Wanbang



Pharmaceutical, provided that the parties have first discussed in good faith and agreed appropriate amendments to the Licence Agreement to reflect such change of holder of import authorisation.

It is expected to take between 35 months to 60 months from the date of Wanbang Pharmaceutical submitting the documentation for obtaining the import drug licence from NMPA.

### Payments

Pursuant to the Licence Agreement, the Group, acting through Solutions, will be eligible to receive payments of up to US\$38 million (or approximately HK\$296.4 million), excluding royalties after hitting certain milestones related to the PRC roll-out. Specifically, Solutions will be eligible to receive the following (payable within 30 business days of receipt of invoice):

## Signature Payment

• A payment of US\$1,000,000 (or approximately HK\$7,800,000) following the date of execution of the Licence Agreement.

#### Development Milestone Payments

- A payment of US\$4,000,000 (or approximately HK\$31,200,000) upon obtaining NMPA approval to conduct a human clinical trial of a licensed product or written NMPA acceptance as sufficient of provided data without need for conducting a further clinical trial, which, in either case, is expected within 6 months of NMPA approval to submit the investigational new drug (IND) application for human clinical trial of a licensed product at NMPA.
- A payment of up to US\$6,000,000 (or approximately HK\$46,800,000) as a registration milestone upon receipt from NMPA of the approval of an import drug licence in respect of a licensed product.
- A payment of US\$2,000,000 (or approximately HK\$15,600,000) upon the First Commercial Sale in the Territory.

#### Commercial Milestone Payment

• A possible payment of up to US\$25,000,000 (or approximately HK\$195,000,000) in total upon achievement of certain annual net sales milestones, dependent on the net sales achieved by Wanbang Pharmaceutical.



# Further Payments and Royalties

In addition, Wanbang Pharmaceutical shall also pay to Solutions:

- 25 percent of net receipts; and
- tiered percentage royalties on net sales, ranging from the low to high teens, except that lower payment structures will apply in certain circumstances where a generic product has successfully entered and impacted the market in the Territory.

#### Possible Refunds

In limited circumstances, up to: (i) 100 per cent. of the US\$1,000,000 (or approximately HK\$7,800,000) signature payment; and (ii) 50 per cent. of the US\$4,000,000 (or approximately HK\$31,200,000) milestone payment, in each case payable under the Licence Agreement and only in respect of the net amount actually received by Solutions, is refundable to Wanbang Pharmaceutical dependent upon the regulatory progress made with NMPA in respect of the anticipated application to conduct a human clinical trial of Fortacin<sup>™</sup> and, thereafter, the success or otherwise in respect of the import drug licence.

#### Exclusivity

Pursuant to the Licence Agreement and subject to the terms and conditions thereof, Solutions has granted to Wanbang Pharmaceutical: (i) an exclusive licence (including with regard to Solutions) to register and file for regulatory approvals in relation to Fortacin<sup>™</sup> solely in the name of Solutions; (ii) an exclusive licence to market, offer for sale, sell, have sold, supply, distribute, import and conduct phase 4 clinical trials in relation to Fortacin<sup>™</sup>; and (iii) a non-exclusive licence to develop, keep, use, have used and export Fortacin<sup>™</sup>.

Against the grant of such exclusive licence, among other things, during the term of the Licence Agreement, Wanbang Pharmaceutical has agreed not to, and shall procure that its affiliates shall not, either themselves or with a third party, and shall not in any way assist any third party to, develop, seek regulatory approval for, manufacture, use, sell (or have sold), market, promote, import, export or otherwise commercialise a competing product in the Territory, provided that: (i) this restriction shall in no way limit Wanbang Pharmaceutical's or its affiliates' or sub-licensees' ability to exploit the rights granted under the Licence Agreement referred to in the paragraph immediately above; (ii) this restriction shall not apply to any affiliate of Wanbang Pharmaceutical who is: (a) engaged solely in the business of providing contract research organisation services to a third party involving a competing product; or (b) a distributor of a competing product as at the



date of the Licence Agreement (either on-line or otherwise), provided that such distributor does not make a royalty or other payment with respect to the sale of the competing product in consideration for any licence under any intellectual property rights of any third party with respect to such competing product; or (c) a hospital or pharmacy where a competing product may be sold and dispensed, provided that such affiliates do not also import any medicinal products, manufacture any medicinal products, or conduct any activities in connection with seeking regulatory approval for, marketing, or promoting, any medicinal products of any nature.

## **Termination, Warranties and Indemnities**

The Licence Agreement shall be effective from the date hereof and is for an indefinite period, containing customary provisions in respect of termination. In addition, the Licence Agreement contains various warranties and indemnities as are customary for such an agreement.

The Group will keep Shareholders and investors updated on the progress made by Wanbang Pharmaceutical in respect of the necessary regulatory approvals in the Territory and the likely commercial launch date for the Territory as and when such details become known.

# MANUFACTURING AND SUPPLY AGREEMENT

The Company is also pleased to announce that Wanbang Pharmaceutical has on 3 December 2018 (after market close in Hong Kong) entered into a manufacturing and supply agreement with PSNW for the manufacture and supply of Fortacin<sup>™</sup> for Wanbang Pharmaceutical. The agreement is for an initial period of 5 years but will continue thereafter unless terminated.

Subject to further agreement between the parties to the Licence Agreement, Solutions may license the manufacturing know-how in the possession and control of Solutions to Wanbang Pharmaceutical or its affiliates in order to have Fortacin<sup>™</sup> manufactured in the Territory.

Fortacin<sup>™</sup> is the first European Union approved prescription treatment for premature ejaculation that does not act on the central nervous system and has been available in the United Kingdom by way of prescription since November 2016. The treatment is a topical spray containing low doses of two anaesthetics – lidocaine and prilocaine – that take effect almost immediately upon application, giving users more control without reducing pleasure.

Jamie Gibson, Chief Executive Officer of Regent Pacific, said, "It is estimated that Fortacin™ has the potential to help an initial target market of approximately 9 million patients in China in its first year of launch, growing to over 170 million patients by its tenth year. We have a strong partner in Wanbang Pharmaceutical, who benefits from being part of the Fosun network. This company has the marketing expertise, established e-commerce platforms and an unrivalled national



distribution network of hospitals, clinics and pharmacies to help ensure the commercial success of Fortacin™ in China."

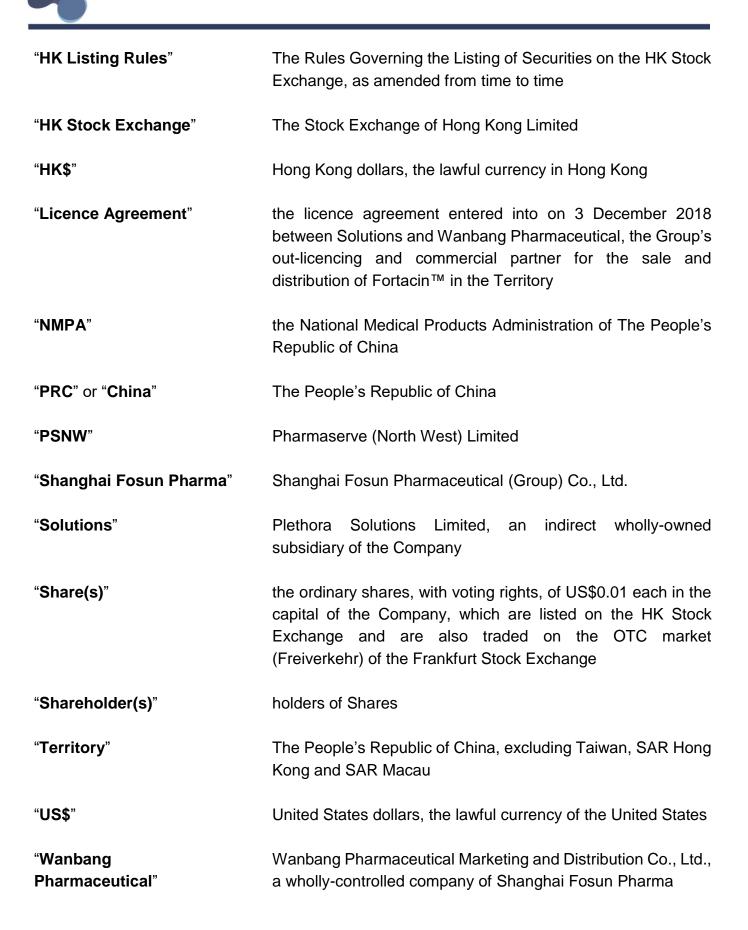
Shareholders of the Company and potential investors are advised to exercise caution when dealing in the Shares.

#### DEFINITIONS

In this announcement, the following expressions have the following meanings unless the context require otherwise:

"Board"	the board of directors of the Company
"Company" or "Regent Pacific"	Regent Pacific Group Limited, a company incorporated in the Cayman Islands with limited liability, the Shares of which are listed on the HK Stock Exchange and are also traded on the OTC market (Freiverkehr) of the Frankfurt Stock Exchange
"CPP"	the Certificate of Pharmaceutical Product issued in the format recommended by the World Health Organization (WHO) in respect of Fortacin <sup>™</sup> the subject of the European Marketing Authorisation. Such CPP establishes the status of Fortacin <sup>™</sup> and of the applicant for this certificate in the exporting territory
"Director(s)"	the directors of the Company
"First Commercial Sale"	the date of the first commercial sale by Wanbang Pharmaceutical or its affiliate (but excluding Solutions and Solutions' affiliates and sub-licensees and contractors engaged by Solutions) to a third party for end use or consumption or further distribution of Fortacin <sup>™</sup> which has been approved by the relevant regulatory authority in the Territory
"Fortacin™ <sup>"</sup>	Fortacin <sup>™</sup> or whatever trade mark is ultimately agreed between the parties to the Licence Agreement as being the trade mark to be used for the licenced product in the Territory
"Group"	the Company and its subsidiaries







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

#### Forward Looking Statements

This announcement, including any information included or incorporated by reference in this announcement, contains statements about Regent Pacific that are or may be forward looking statements. Such forward looking statements involve risks and uncertainties that could significantly affect expected results and are based on certain key assumptions. Many factors could cause actual results to differ materially from those projected or implied in any forward looking statement. Much of the risk and uncertainty relates to factors that are beyond Regent Pacific's abilities to control or estimate precisely, such as future market conditions and the behaviours of other market participants, and therefore undue reliance should not be placed on such statements. Neither Regent Pacific nor any of its associates or directors, officers, employees, managers, agents, representatives, partners, members, consultants or advisers: (i) provide any representation, warranty, assurance or guarantee that the occurrence of the events expressed or implied in any forward looking statement will actually occur; nor (ii) assume any obligation to, and do not intend to, revise or update these forward looking statements, except as required pursuant to applicable law, the HK Listing Rules or other applicable regulation. Regent Pacific disclaims any obligation to update any forward looking or other statements contained herein, except as required by applicable law, the HK Listing Rules or other applicable regulation.

#### No Profit Forecasts or Estimates

No statement in this announcement is intended as a profit forecast or estimate for any period and no statement in this announcement should be interpreted to mean that earnings or earnings per share for Regent Pacific for the current or future financial years would necessarily match or exceed the historical published earnings or earnings per share for Regent Pacific. Regent Pacific does not undertake to update information contained in this announcement, except as required by applicable law, the HK Listing Rules or other applicable regulation.

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>

- \* Non-Executive Directors
- # Independent Non-Executive Directors

Hong Kong, 3 December 2018