



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

Stock Code: 0575

3 October 2017

## ANNOUNCEMENT



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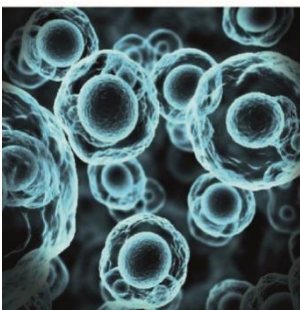
### **AMENDED AND RESTATED LICENCE AGREEMENT WITH RECORDATI AND COMMERCIAL LAUNCH OF FORTACIN™ IN EUROPE BY RECORDATI**



#### **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 announcement dated 14 August 2017 and are pleased to inform the shareholders of the Company and potential investors that on 3 October 2017 (after market close in Hong Kong) Holdings and Solutions, both wholly owned subsidiaries of the Company, entered into an Amended and Restated Licence Agreement with Recordati, the Group's out-licencing and commercial partner for the sale and distribution of Fortacin™ in Europe, amending and restating the Previous Agreement entered into with Recordati on 16 September 2014 and effective from 26 September 2014, in respect of the rights to commercialise Fortacin™, Solutions' novel treatment for premature ejaculation, in Europe, Russia, the Commonwealth of Independent States (C.I.S), Turkey and certain countries in North Africa.



Solutions continues to retain full commercialisation rights for Fortacin™ for the rest of the world, including but not limited to the US and Canada, Latin America, the Asia Pacific region, the Middle East and Sub-Saharan Africa.

As foreshadowed in the Company's announcement on 14 August 2017, pursuant to the Amended and Restated Licence Agreement, the Group, acting through Solutions (a wholly owned subsidiary of the Company), will be eligible to receive payments of up to €41 million (or approximately US\$48.31 million or HK\$376.82 million) plus royalties after hitting certain milestones related to the European roll-out. Specifically, Solutions will be eligible to receive:

- a payment of €4 million (or approximately US\$4.71 million or HK\$36.74 million) on the date on which the Amended and Restated Licence Agreement becomes effective;
- a payment of up to €4 million (or approximately US\$4.71 million or HK\$36.74 million) in total upon first commercial sales of the Fortacin™ product in France, Germany, Italy, Spain and Portugal (€800,000 (or approximately US\$943,000 or HK\$7.36 million) for each of these 5 countries);
- a possible payment of up to €8 million (or approximately US\$9.43 million or HK\$73.55 million) in total, dependent on the net sales achieved by Recordati in the first 3 years of sales;
- up to €25 million (or approximately US\$29.46 million or HK\$229.79 million) in aggregate in sales-based milestones; and
- tiered percentage royalties on net sales, ranging from the mid-teens to the mid-twenties for 10 years from first commercial sale, and thereafter at a single digit percentage royalty rate.

While the Directors can confirm that there are no material amendments to the anticipated terms set out in the Company's announcement dated 14 August 2017 when compared against those contained in the Amended and Restated Licence Agreement, shareholders and investors should read the whole text of this announcement, including the section entitled "Summary of Amended and Restated Licence Agreement".

As previously announced, the Directors can confirm that it remains Recordati's intention to launch Fortacin™ for commercial sale in Europe 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.

The Company is also pleased to announce that Recordati and Solutions have on 3 October 2017 (after market close in Hong Kong) entered into an amended development, manufacturing and supply agreement with PSNW for the development, manufacture and supply of the Fortacin™ product for Recordati and Solutions. This amended agreement amends certain terms and conditions to bring them in line with the Amended and Restated Licence Agreement, including the manufacture and supply of the 12 dose product under the 100 litre scale and the 300 litre scale. The agreement remains for an initial period of 5 years but will continue thereafter unless terminated and amends the development, manufacturing and supply agreement entered into between Solutions and PSNW on 26 September 2014.

**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).

### **Amended and Restated Licence Agreement**

The Directors refer to the announcement dated 14 August 2017 and are pleased to inform the shareholders of the Company and potential investors that on 3 October 2017 (after market close in Hong Kong) Holdings and Solutions, both wholly owned subsidiaries of the Company, entered into an Amended and Restated Licence Agreement with Recordati, the Group's out-licensing and commercial partner for the sale and distribution of Fortacin™ in Europe, amending and restating the Previous Agreement entered into with Recordati on 16 September 2014 and effective from 26 September 2014, in respect of the rights to commercialise Fortacin™, Solutions' novel treatment for premature ejaculation, in Europe, Russia, the Commonwealth of Independent States (C.I.S), Turkey and certain countries in North Africa. Solutions continues to retain full commercialisation rights for Fortacin™ for the rest of the world, including but not limited to the US and Canada, Latin America, the Asia Pacific region, the Middle East and Sub-Saharan Africa.

As foreshadowed in the Company's announcement on 14 August 2017, pursuant to the Amended and Restated Licence Agreement, the Group, acting through Solutions (a wholly owned subsidiary of the Company), will be eligible to receive payments of up to €41 million (or approximately US\$48.31 million or HK\$376.82 million) plus royalties after hitting certain milestones related to the European roll-out. Specifically, Solutions will be eligible to receive:

- a payment of €4 million (or approximately US\$4.71 million or HK\$36.74 million) on the date on which the Amended and Restated Licence Agreement becomes effective;
- a payment of up to €4 million (or approximately US\$4.71 million or HK\$36.74 million) in total upon first commercial sales of the Fortacin™ product in France, Germany, Italy, Spain and Portugal (€800,000 (or approximately US\$943,000 or HK\$7.36 million) for each of these 5 countries);
- a possible payment of up to €8 million (or approximately US\$9.43 million or HK\$73.55 million) in total, dependent on the net sales achieved by Recordati in the first 3 years of sales;
- up to €25 million (or approximately US\$29.46 million or HK\$229.79 million) in aggregate in sales-based milestones; and
- tiered percentage royalties on net sales, ranging from the mid-teens to the mid-twenties for 10 years from first commercial sale, and thereafter at a single digit percentage royalty rate.

While the Directors can confirm that there are no material amendments to the anticipated terms set out in the Company's announcement dated 14 August 2017 when compared against those contained in the Amended and Restated Licence Agreement, shareholders and investors should read the whole text of this announcement, including the section entitled "Summary of Amended and Restated Licence Agreement" set out immediately below.

The Amended and Restated Licence Agreement shall be effective from the date thereof.

For further details relating to the terms of the Amended and Restated Licence Agreement, shareholders and investors should refer to the section entitled "Summary of Amended and Restated Licence Agreement", which appears below within this announcement.

### **Summary of Amended and Restated Licence Agreement**

A summary of the material changes made to the Previous Agreement pursuant to the Amended and Restated Licence Agreement is set out below.

With effect from 3 October 2017 Solutions, Holdings, and Recordati have amended and restated their Previous Agreement which was originally entered into on 16 September 2014 (and had an effective date of 26 September 2014).



At the time of entering the Previous Agreement the then-current formulation of Fortacin™ was an aluminium spray container with a metering valve containing 6.5ml of solution delivering approximately 20 doses. It was intended that a formulation delivering approximately 6 doses would be developed and commercialised and the then-current European Marketing Authorisation would be varied by Solutions accordingly. The Amended and Restated Licence Agreement provides that a formulation delivering 12 doses will be developed and commercialised. In connection with this re-formulation, the parties agreed to conduct an initial manufacturing scale-up to 100 litre scale, and a variation to the European Marketing Authorisation was approved by the European Medicines Agency. The cost of this was initially borne by Solutions but shall now be reimbursed in full by Recordati. It has also been agreed that a further manufacturing scale-up to 300 litre scale shall be conducted at Solutions' cost. With the agreement of Recordati, Solutions placed the product on the market in the United Kingdom on 10 November 2016 in order to maintain the European Marketing Authorisation in force.

The Previous Agreement provided that upon acceptance of the variation to the European Marketing Authorisation (from a 20 dose formulation to a 6 dose formulation), the European Marketing Authorisation would be transferred to Recordati and Solutions would receive €6 million (or approximately US\$7.07 million or HK\$55.15 million) (“**Development Payment**”). The Amended and Restated Licence Agreement now provides that Solutions shall receive €4 million (or approximately US\$4.71 million or HK\$36.74 million) promptly after signing the Amended and Restated Licence Agreement and the European Marketing Authorisation will be transferred to Recordati as soon as possible following the effective date of the Amended and Restated Licence Agreement and to this end Solutions shall, on the same date, file with the applicable regulatory authority(ies), at Solutions' own expense, all documentation necessary to transfer the European Marketing Authorisation to Recordati. Prior to such transfer, Recordati shall have the right to commercialise Fortacin™ as Solutions' exclusive distributor and will be responsible for reimbursing Solutions for any externally invoiced costs and expenses paid by Solutions in respect of any necessary variations to and any renewal of the European Marketing Authorisation applied for by Solutions during this interim period.

Previously it was agreed that Solutions would receive a total of €10 million (or approximately US\$11.781 million or HK\$91.88 million) following first commercial sale of the Fortacin™ product in France, Germany, Italy, Portugal and Spain (“**Launch Payments**”). This has now been amended to provide that a total of €4 million (or approximately US\$4.71 million or HK\$36.74 million) will be due in this event (except that €1 million (or approximately US\$1.18 million or HK\$9.20 million) may be withheld until an aggregate total of three batches manufactured at 300 litre scale comply with the currently registered release specification indicating validation of manufacture at such scale). Based on the Previous Agreement, Solutions would have received €16 million (or approximately US\$18.85 million or HK\$147.03 million) in respect of the

Development Payment and the Launch Payments but will now receive €8 million (or approximately US\$9.43 million or HK\$73.55 million), leaving an €8 million (or approximately US\$9.43 million or HK\$73.55 million) shortfall (“**Clawback**”). The Clawback can be received by Solutions either in full or partially following the expiry of three years after the first commercial sale of the Fortacin™ product by Recordati where the value of net sales achieved by Recordati reaches the level anticipated under the Previous Agreement.

In the Previous Agreement it was provided that Solutions would receive payments of up to €25 million (or approximately US\$29.46 million or HK\$229.79 million) upon achievement by Recordati of various aggregate net sales targets, this has now been amended such that both the relevant payments and the aggregate net sales targets have been reduced to €15.6 million (or approximately US\$18.38 million or HK\$143.36 million). If, however, in any of the first three years after the first commercial sale of the Fortacin™ product by Recordati, the value of sales achieved by Recordati reaches the level anticipated under the Previous Agreement, the payments and thresholds shall return to their originally agreed level.

Royalties due under the Previous Agreement during an initial royalty term remain the same, however, pursuant to the amendments to the Amended and Restated Licence Agreement these will be applied on reduced threshold amounts of annual net sales, subject to the Clawback. If, however, in any of the first three years after the first commercial sale of the Fortacin™ product by Recordati, the value of sales achieved by Recordati reaches the level anticipated under the Previous Agreement, the threshold amounts shall return to their originally agreed level.

### **Amended Development, Manufacturing and Supply Agreement**

Solutions is also pleased to announce that Recordati, a subsidiary of Recordati, and Solutions have on 3 October 2017 (after market close in Hong Kong) entered into an amended development, manufacturing and supply agreement with PSNW for the development, manufacture and supply of the Fortacin™ product for Recordati and Solutions. This amended agreement amends certain terms and conditions to bring them in line with the Amended and Restated Licence Agreement, including the manufacture and supply of the 12 dose product under the 100 litre scale and the 300 litre scale. The agreement remains for an initial period of 5 years but will continue thereafter unless terminated and amends the development, manufacturing and supply agreement entered into between Recordati, Solutions and PSNW on 26 September 2014.

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

As previously announced, the Directors can confirm that it remains Recordati’s intention to launch Fortacin™ for commercial sale in Europe 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.

Fortacin™ is the first EU approved prescription treatment for premature ejaculation (“PE”) that does not act on the central nervous system and has been available in the UK 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,** “The finalisation of the amended licence agreement is a positive step for Regent Pacific as we prepare to roll out Fortacin™ in Europe next year. The agreement further demonstrates the confidence we and our commercial partners have in the treatment, as well as our collective commitment to a broader distribution of Fortacin™ in several other markets across the globe in the months and years to come.”

### **Update on “out-licensing”**

As previously disclosed, discussions and negotiations are continuing to take place in respect of “out-licensing” the grant of rights by Solutions with pharmaceutical companies and with other strategic partners in respect of Fortacin™ in other major territories outside of the UK and EU, including China. While it remains impossible to determine with accuracy the timing of completion of such agreements (and no assurance can be given that negotiations will lead to a binding licence agreement(s)), the Company anticipates that such discussions and negotiations will be assisted by Fortacin™ being brought to market in mainland Europe, which is expected to occur in early 2018. The Company will update shareholders and the market more generally if and when there are any relevant developments in this respect.

**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:

<b>“Amended and Restated Licence Agreement”</b>	the amended and restated licence agreement entered into between Holdings, Solutions and Recordati, the Group’s out-licencing and commercial partner for the sale and distribution of Fortacin™ in Europe, on 3 October 2017, amending and replacing the Previous Agreement
<b>“Board”</b>	the board of directors of the Company
<b>“Company”</b>	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
<b>“Director(s)”</b>	the directors of the Company
<b>“European Marketing Authorisation”</b>	means the marketing authorisation issued by the EMA, number EMEA/H/C/002693 (issued on 15 November 2013), which, as at the Effective Date, is held by Solutions
<b>“EUR” or “€”</b>	Euro
<b>“Group”</b>	the Company and its subsidiaries
<b>“HK Listing Rules”</b>	The Rules Governing the Listing of Securities on the HK Stock Exchange, as amended from time to time
<b>“HK Stock Exchange”</b>	The Stock Exchange of Hong Kong Limited
<b>“HK\$”</b>	Hong Kong dollars, the lawful currency in Hong Kong
<b>“Holdings”</b>	Plethora Solutions Holdings PLC
<b>“Previous Agreement”</b>	the licence agreement entered into with Recordati, the Group’s out-licencing and commercial partner for the sale and distribution of Fortacin™ in Europe, on 16 September 2014 and effective from 26 September 2014, in respect of the rights to commercialise Fortacin™, Solutions' novel treatment for premature ejaculation, in Europe, Russia, the Commonwealth of Independent States (C.I.S), Turkey and certain countries of



	North Africa
“PSNW”	Pharmaserve (North West) Limited
“Recordati”	Recordati Group
“Solutions”	Plethora Solutions Limited
“Share(s)”	the ordinary shares, with voting rights, of US\$0.01 each in the capital of the Company, which are listed on the HK Stock Exchange and are also traded on the OTC market (Freiverkehr) of the Frankfurt Stock Exchange
“US\$”	United States dollars, the lawful currency of the United States

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\$1.1782; 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*)\*  
Jamie Gibson (*Chief Executive Officer*)  
David Comba#  
Julie Oates#  
Mark Searle#  
Jayne Sutcliffe\*

\* *Non-Executive Directors*

# *Independent Non-Executive Directors*

Hong Kong, 3 October 2017