



**Regent Pacific Group Limited** 

COMPANY OVERVIEW March 2019

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## Our Strengths & Ambitions

- A focussed healthcare investment vehicle listed on the main board of the Hong Kong Stock Exchange
- Strong opportunistic management team and proven transaction track record having returned over US\$298 million to shareholders since listing in May 1997
- Average cash returns generated over the term of investment of nearly two times on material investment disposals over the last 6.5 years from mid 2009 to 2015
- Our stated strategy is to transform our portfolio to healthcare by being acquisitive with the Plethora take-over being the first
- Our core product is Fortacin<sup>™</sup>, a European, Hong Kong and Macau approved treatment for Premature Ejaculation that has the potential to be the next Viagra, with market potential of up to US\$2.1 billion per annum
- Hong Kong listing has us ideally placed to capitalise on the healthcare boom in China
- We have a proven track record of completing M&A and ECM transactions and have a stated ambition to continue to expand into healthcare



HK Stock Code (0575 HK ) Strong shareholder base, supported by: -Chairman (James Mellon);

-CEO (Jamie Gibson); and

-CSO (Mike Wyllie),

who collectively own 26%\*



#### \*as at 29 March 2019 \*\*based on our annual results announcement for year ended 31 December 2018

### **REGENT CAPITALISATION**

Share price*	HK\$0.27
52 week low - high*	HK\$0.229 – HK\$0.46
Total issued share capital*	1,837 million
90 Day Average Daily Volume*	*
Market cap*	HK\$496 million (US\$63.60million)
Cash & listed/unlisted securitie	es**US\$6.81 million
Debt**	Nil

### **LTM SHARE PRICE PERFORMANCE\***



### **Regent Pacific Group Board and Management**



#### JAMES MELLON Non-Executive Chairman

- Specialist in the development and restructuring of international investment vehicles with over 20 years' investment experience in Asia
- Well known and respected global healthcare investor

### **MARK SEARLE**

Independent Non-Executive Director

 Over 30 years' experience in the investment management industry

### JAMIE GIBSON

Chief Executive Officer

• Specialist in corporate finance, direct equity investments and structuring emerging market investment products

**DAVID COMBA** 

Independent Non-Executive Director

• Geologist who served on or led mineral exploration teams that have made eleven significant discoveries of base and precious metals

### **Dr. MIKE WYLLIE** Chief Scientific Officer

- Co-founder of Plethora
- Over 25 years experience with the pharma industry with Pfizer and American Home Products
- Involved with new product inception, drug discovery and safety testing, clinical development, regulatory filing etc.., including Viagra® and Cardura®

### JULIE OATES

Independent Non-Executive Director

• Chartered accountant with experience in accounting and business assurance as well as offshore corporate and trust administration

#### **JAYNE SUTCLIFFE**

Non-Executive Director

 Spent most of her professional career in the fund management industry specialising in sales and marketing

### **Creating a HK Listed Healthcare Business**

- Vision to create a healthcare company serving the dynamic global healthcare market
- Regent has the management and track record to build a strong healthcare portfolio
- The Group is committed to divesting of non-core assets and investments to enable the Company to pursue growth and opportunistic investments in the life sciences sector<sup>1</sup>
- Spending on healthcare in China is projected to grow from US\$357 billion in 2011 to US\$1 trillion in 2020<sup>2</sup>
- By some estimates China became the second-largest global consumer of medicines in 2017 market is worth US\$122.6bn<sup>3</sup>
- The Chinese National Medical Products Administration (NMPA formerly CFDA) has been overhauled, which means for foreign firms quicker and cheaper drug approvals
- Favourable demographic trends, continuing urbanisation, an increasing disease burden, the overall economy's healthy expansion, and income growth are driving the increase in healthcare spend<sup>2</sup>
- A shortage of investible companies on the Hong Kong market, combined with high Chinese domestic interest in healthcare, influences valuations for companies in this sector
- Licence agreement with Fosun / Wanbang Pharmaceutical Marketing & Distribution will allow entry into Chinese market and strong partnership to navigate PRC regulatory environment (NMPA)

Healthcare Market

China

Scarcity

High quality assets, tapping into Chinese interest in the healthcare market and strong execution will drive value

PEGENT PACIFIC

Source: 1Regent Pacific Interim Report 2015; 2McKinsey Health care in China: Entering 'uncharted waters' (November 2012); 3KPMC Realth care & life sciences in China – Towards growing collaboration (March 2013); 4FactSet (7 March 2016)

# Plethora Solutions

### **FORTACIN**<sup>™</sup>

- Plethora's lead asset is Fortacin<sup>™</sup>, a novel Rx topical treatment for premature ejaculation, with potential to capture a global market
- Focus is on bringing Fortacin<sup>™</sup> to market through strategic commercial partners through 'out-licensing' agreements
- Fortacin<sup>™</sup> is out-licensed to i) Wanbang Pharmaceutical Marketing & Distribution, a subsidiary of Shanghai Fosun Pharmaceutical (HK:02196) for China, ii) Recordati (REC MI) for Europe, Russia, CIS, Turkey and certain countries of North Africa and iii) Orient EuroPharma for HK, Macau, Taiwan, Singapore and other SE Asian countries
- Recordati commenced commercial sales of Fortacin<sup>™</sup> in Italy, France, Spain, Germany and Portugal in 2018
- Fortacin<sup>™</sup> is expected to be available in the UK, Greece, Romania, Czech Republic, Slovak Republic and Poland in the second half of 2019
- Obtained a valid import licence in 2018 to allow for the sale of Fortacin<sup>™</sup> in Hong Kong and Macau, with expected launch in 2019 by Orient EuroPharma
- NDA filing process commenced with FDA, with approval targeted in Q4 '21/Q1 '22



- Licence Agreement signed in December 2018 with Wanbang Pharma to launch Fortacin<sup>™</sup> a breakthrough premature ejaculation treatment in China
- 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 to receive up to \$13 million in upfront licence payments and upon launch of first commercial sales
- Regent Pacific to receive up to \$25 million in sales milestones, together with royalties ranging from low to high-teens
- Wanbang Pharma together with SinoPharma has the largest distribution network with extensive marketing, sales and distribution reach in the PRC via all platforms (pharmacies, hospitals, clinics, online, etc...)
- Wanbang Pharma is responsible at its own expense for obtaining all PRC regulatory approvals, with an expected timeframe of 35 – 40 months from time of document submission
- Regent Pacific retains full commercial rights to Fortacin<sup>™</sup> in all unlicensed countries, including the USA



"A male sexual dysfunction" characterized by: ejaculation that always or nearly always occurs prior to or within about one minute of vaginal penetration; the inability to delay ejaculation on all or nearly all vaginal penetrations; and negative personal consequences such as distress, bother, frustration and/or the avoidance of sexual intimacy



## Primary Efficacy Measure Intravaginal Ejaculatory Time (IELT):

Normal 4-7 minutes. ISSM definition of PE <1 minute</li>

Premature ejaculation is possibly the most prevalent sexual dysfunction affecting 1 in 4 men

- Estimated to be equal to or greater than erectile dysfunction
- Estimated at 30-45m men in EU, 30m in USA and over 100m in China

## No properly effective treatment is approved widely for this condition

- Off-label use of antidepressants, topical anesthetic creams, monograph, all subject to little efficacy
- Priligy (SSRi) associated with 90% discontinuation; only approved in limited EU territories and failed to gain US FDA approval

### **FORTACIN<sup>™</sup> Overview**



Therapeutic

Regulatory

Market Potential

- Topical aerosol formulation of Lidocaine 7.5mg + Prilocaine 2.5mg
- Restores ejaculatory reflex from 32-34 seconds pre-treatment to 3-4 minutes (normal) almost immediately and effects are maintained on long term treatment

- Out licensed Fortacin<sup>™</sup> to i) **Wanbang Pharma** (a subsidiary of Shanghai Fosun Pharma) for China, ii) **Recordati**, a European pharmaceutical group, for Europe, Russia, CIS, Turkey and certain countries of North Africa, and iii) **Orient EuroPharma** for HK, Macau, Taiwan, Singapore and other SE Asian countries
  - Fortacin<sup>™</sup> has commenced commercial sales in Italy, France, Spain, Germany and Portugal in 2018 through our commercial partner Recordati with Fortacin<sup>™</sup> being rolled to other European countries in 2019
  - EMA approval received in November 2013 the first topical Rx approved in the EU for PE
  - Acquired a valid import licence to allow for the sale of Fortacin<sup>™</sup> in Hong Kong and Macau in 2018, with launch expected in 2019
  - USA FDA filing process commenced with aim of submitting NDA by Q4' 21, followed by 10 month PDUFA with approval expected in 2022
  - NMPA (CFDA) approval to be managed by Wanbang (at their cost) over next 3 to 4 years



- Potential significant market opportunity, of up to US\$2.1 billion per annum peak sales for US, EU and China (based on internal modelling), Rx only
  - Currently the only approved competitor in Europe is Priligy- SSRi, with significant profile disadvantages as compared to Fortacin<sup>™</sup>
  - Commercial marketing partners are to gain support from KOLs for Fortacin<sup>™</sup> to become 1st line on treatment guidelines where applicable
  - Direct to Consumer (DTC) advertising could cause step change in demand once US FDA approval is obtained in US marketplace



## Two large pivotal trials show highly significant and clinically meaningful effect

- Mean IELT\* at baseline was 0.5 minutes rising to 3.2 minutes at week 12
- 87% of patients considered as responders
- Excellent tolerability in ~ 23,500 doses delivered with no significant safety issues
- Can be used with and without condom

### Strong Efficacy Data

- Restoration of ejaculatory reflex from 32-34 seconds pre-treatment to 3-4 minutes (normal) almost immediately
- Excellent patient and partner responses on measures of distress, control, satisfaction & interpersonal relationship
- Effect durable long term
- No safety or efficacy issues reported by physicians and patients in Europe

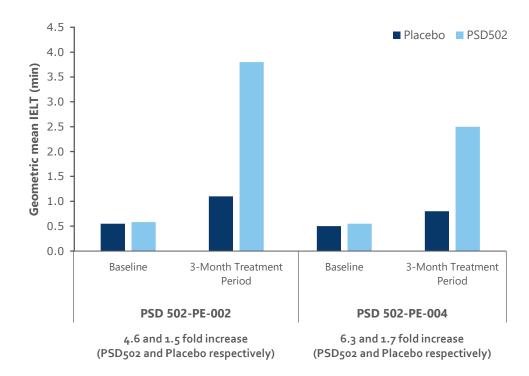
### Eutectic mixture

- Prevents crystallisation to facilitate absorption
- Formulation does not penetrate keratinized skin maintaining sexual sensation for man
- Does not anaesthetise the foreskin





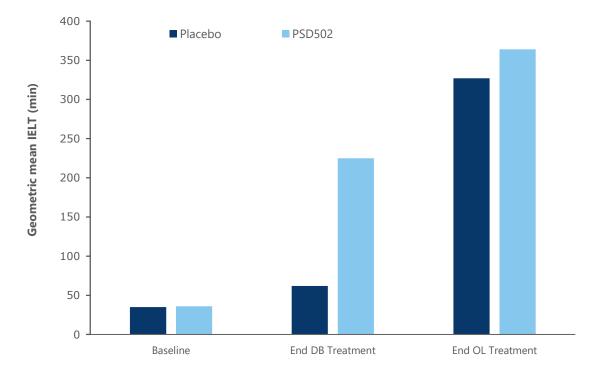
# Significant increase in ejaculatory latency obtained with Fortacin<sup>™</sup> over placebo



	Geometric (min PSD502	utes)	Geometric mean IELT (minutes) PSD502-PE-004		
	Placebo	PSD 502	Placebo	PSD 502	
Baseline	0.53	0.56	0.58	0.60	
3 Months Rx	0.80	2.61	1.07	3.85	

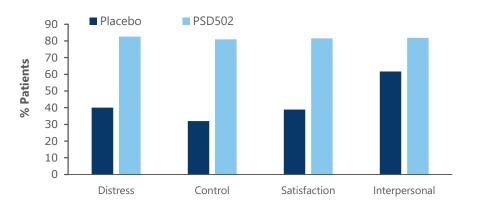


# Significant increase in ejaculatory latency obtained with Fortacin<sup>™</sup> over placebo

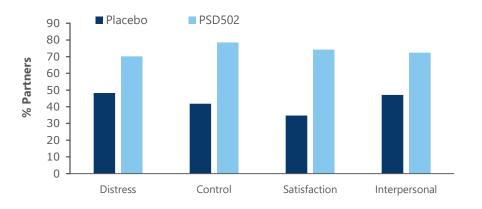


- 3-month double-blind phase: Patients randomised to receive either Fortacin<sup>™</sup> or placebo
- 9-month open-label phase: All patients on Fortacin<sup>™</sup> treatment
- DB Placebo/ OL Fortacin<sup>™</sup> group geometric mean IELT values were shown to gradually increase towards the values of the DB Fortacin<sup>™</sup> / OL Fortacin<sup>™</sup> group

Patients & sexual partners report improvement of  $\geq$  1 point in each PEP domain at the end of month 3







4 item questionnaire validated in subjects with PE\*

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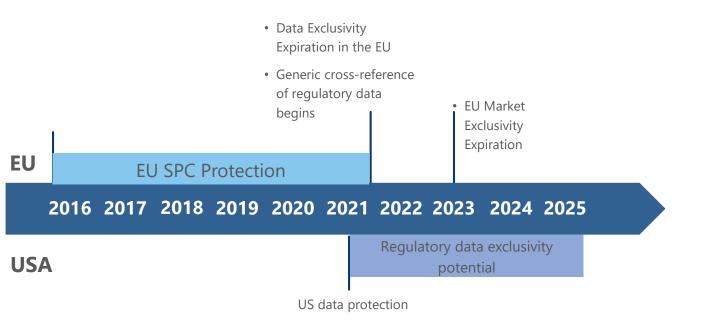
- Separate patient and partner questionnaires
- Each question answered on a 5-point scale
  - Personal distress related to ejaculation
  - Perceived control over ejaculation
  - Satisfaction with sexual intercourse
  - Interpersonal difficulty related to ejaculation

More patients and partners using Fortacin<sup>™</sup> reported improvements of at least one point in each of the PEP domains compared to those using placebo (*P* < 0.001 for all between-treatment comparisons)

Treatment advantage was also seen at the end of months 1 and 2 for all domains

### Patients





- In September 2014, Plethora acquired the remaining rights to Fortacin<sup>™</sup> for US\$25 million resulting in Plethora owning 100% of the rights to Fortacin<sup>™</sup> on a global basis
- European patent covers the formulation of any or all mixtures of local anaesthetics in hydrofluorocarbon propellants (e.g. non CFC propellants)
- Regulatory exclusivity protecting Plethora's data is expected to run for at least 3 years from the date of US FDA approval for Fortacin<sup>™</sup> in the US, though it could be 5 years if the US FDA treats Fortacin<sup>™</sup> as a new chemical entity
- Indication from the FDA that topical use will require full Phase III non-inferiority study (rather than bio-equivalence) to demonstrate equivalence – a substantial barrier against generic entrants
- Wanbang / Fosun to manage NMPA (CFDA) regulatory approval process, with likely timeline of 35 to 40 months for Import Drug approval from submission in 2019



Pharmaserve North West (PSNW) has been secured as the supply chain and manufacturing development partner for the 12-dose canister



### Experience

- PSNW is a leading contract development and manufacturing organisation (CDMO) specialising in the development and manufacture of metered dose inhalers (MDIs), dry powder inhalers (DPIs) and other pharmaceutical aerosols.
- MHRA approved in the EU and PSNW is in the process of obtaining GMP certification from the United States Food and Drug Administration





## **PRC Regulatory Process**



## **Key Considerations**

- Clinical studies conducted under Investigational New Drug (IND) programme for Imported Drug and in full consultation with NMPA
- Approval process would be approximately 12 to 14 months quicker if NMPA accept clinical data from European Medicines Agency as only Pharmacokintic study required to verify no medically relevant difference between ethnic Chinese and Western patients.



Q1 '21

## **US Regulatory Process**



## **Key Considerations**

- A phase II (Pilot) Multi-center, Randomized, Double-Blind Study on 100 patients comparing the proportion of responders to PSD502 and to placebo using the PEBEQ In subjects with **Premature Ejaculation**
- This study is being done to test the effect of Fortacin<sup>™</sup> medication compared to placebo in subjects with premature ejaculation. Half of the subjects will receive Fortacin<sup>™</sup> and half will receive placebo.
- Need to satisfy drug combination rules; use eutectic properties to meet
- Multiple clinical endpoints IELT and patient reported outcome (PRO) measures all demonstrate clinical and statistical significance



- The studies will assess whether the bothersome symptoms of premature ejaculation (PE) are helped when treated with Fortacin<sup>™</sup> by answering questionnaires such as the 'Premature Ejaculation Bothersome Evaluation Questionnaire' (PEBEQ) and 'Index of Premature Ejaculation© (IPE) and some additional questions about premature ejaculation
- The studies will also measure the effect of Fortacin<sup>™</sup> on the Intravaginal Ejaculatory Latency Time (IELT). This is the time between when the penis enters the vagina and when the subject starts to ejaculate in the vagina
- Subjects are stratified based on whether they are circumcised or uncircumcised and within each stratified group subjects are randomized to Fortacin<sup>™</sup> (lidocaine prilocaine spray) or placebo in a 1:1 ratio
- Primary Outcome Measures: Change between Baseline and 4 weeks : Success on the Premature Ejaculation Bothersome Evaluation Questionnaire PEBEQ Item 3 (event-specific bother)

Time Frame: Baseline and 4 week treatment period: Success is defined as having a 1-point or greater improvement between the mean response over the treatment period and the mean response during the baseline period

• Phase II study will have 100 patients and the phase III study will have 172 patients

### **Pricing Considerations**



Therapeutic	US\$ Price per usage	US\$ Price per script	
Fortacin™ US market <sup>#</sup>	\$20 (3 sprays=1 dose)	\$240 (12 doses)	
Fortacin™ EU5 market*	\$4.50 to \$6 (3 sprays=1 dose)	\$54 to \$72 (12 doses)	
ED Competitors <sup>1</sup>	US: \$67 - \$71 (per dose)	US: \$402 to \$424 (6 doses) EU4 (ex-factory): \$36 to \$168 (12 doses)	
ED Competitors	EU4 (ex-factory): \$3 to \$14 (per dose) France (public price): \$12 to \$18	France (public price): \$144 to \$216	
Priligy <sup>®2</sup>	EU3 Ex-Factory (Germany, Italy & Spain): \$4 to \$7 France public price \$24 to \$28	EU3 Ex-Factory (Germany, Italy & Spain): \$48 to \$84 France public price: \$288 to \$336	

- Price corridor for ED drugs is fairly wide amongst EU4 (average ranges from US\$36 to US\$168)<sup>▼</sup>
- Germany is 4% to 21% above the EU4 average for most of the ED drugs
- UK and Italy are commonly (2% to 40%) below the EU4 average
- Plethora expect healthcare authorities will not reimburse Fortacin<sup>™</sup> in the major markets, so largely a cash market and potentially seen as a lifestyle drug
- Key for Plethora's commercial marketing partners is to gain support from KOLs for Fortacin<sup>™</sup> to become 1st line on treatment guidelines where applicable



## US ED Drugs Price Summary

	Cost per Pill				Treatment Cost - Ex-Factory (6 pills)				0/ 10 000 000
Product	Launch	Oct / Nov 2013	Feb 2016	Current Prices (Jan 2019)	Launch	Oct / Nov 2013	Feb 2016	Current Prices (Jan 2019)	% Increase since Feb 2016
Viagra (100mg)	\$7	\$27	\$43	\$71	\$42	\$160	\$257	\$424	65%
Cialis (10mg /20mg)	\$8	\$29	\$46	\$67	\$48	\$174	\$275	\$402	46%
Cialis Daily (2.5mg / 5mg) <b>(30 pills)*</b>	\$4	\$5	\$8	\$11	\$113	\$150	\$240	\$330	38%
Levitra (20mg)	\$8	\$26	\$42	\$52	\$46	\$153	\$248	\$309	24%

\*Cialis Daily Treatment Costs is 30 pills instead of 6 pills



### Male Sexual Function Landscape

### **Competitive Market**

AVAILABLE PE TREATMENTS	FORTACIN™	PRILIGY	MONOGRAPH PRODUCTS	OFF LABEL PRODUCTS	
Product	Topical aerosol formulation of Lidocaine 7.5mg + Prilocaine 2.5mg	Orally-administered dapoxetine	Lidocaine spray products (Promescent, Stud-100)	SSRIs (must almost always be used with condom)	
Regulatory Approval	Approved in EU, HK and Macau and pending FDA approval	Approved in EU and other countries	N/A	N/A	
Onset Time	Almost immediately	1-3 hours	10 – 60 minutes	20-30 minutes	
Side Effects	Side EffectsExcessive numbing (only 4.5% patients)		Excessive numbing leading to loss of sensitivity and erection, skin irritation, burning	High risk of numbing leading to loss of sensitivity and erection	

### **Comparative Market**

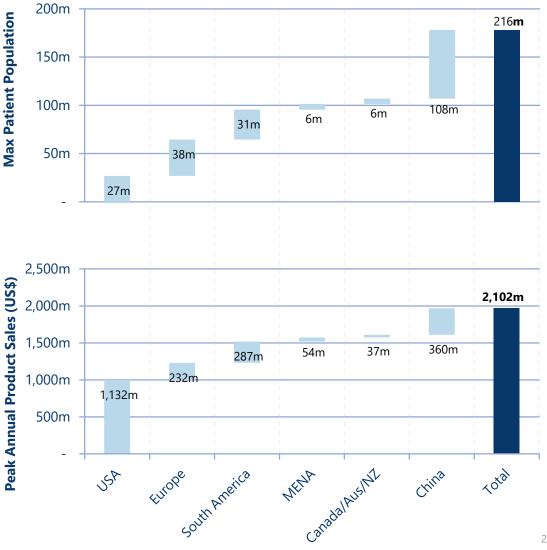
US RETAIL SALES ED MARKET	2012	2013	2014	2015	2016	2017	2018
# of Rx Scripts	19.0 million	18.1 million	16.0 million	14.8 million	15.1 million	13.6 million	14.5 million
Cialis	US\$1,259,928,704	US\$1,517,928,576	US\$1,762,138,240	US\$2,134,897,408	US\$2,832,581,785	US\$2,983,714,720	US\$2,984,267,501
Viagra	US\$1,419,078,784	US\$1,604,324,864	US\$1,691,691,648	US\$1,907,254,016	US\$3,196,218,191	US\$4,365,284,742	US\$5,973,591,827
Levitra	US\$351,986,272	US\$290,867,648	US\$224,803,952	US\$210,830,416	US\$204,145,983	US\$173,442,117	US\$129,608,722
TOTAL	US\$3,030,993,760	US\$3,413,121,088	US\$3,678,633,840	US\$4,252,981,840	US\$6,232,945,959	US\$7,522,441,579	US\$9,087,468,050

Source: MME - 2012 to 2013 accessed on April 2016, 2014 to 2015 accessed on March 2016, 2016 to 2018 accessed on January 2019



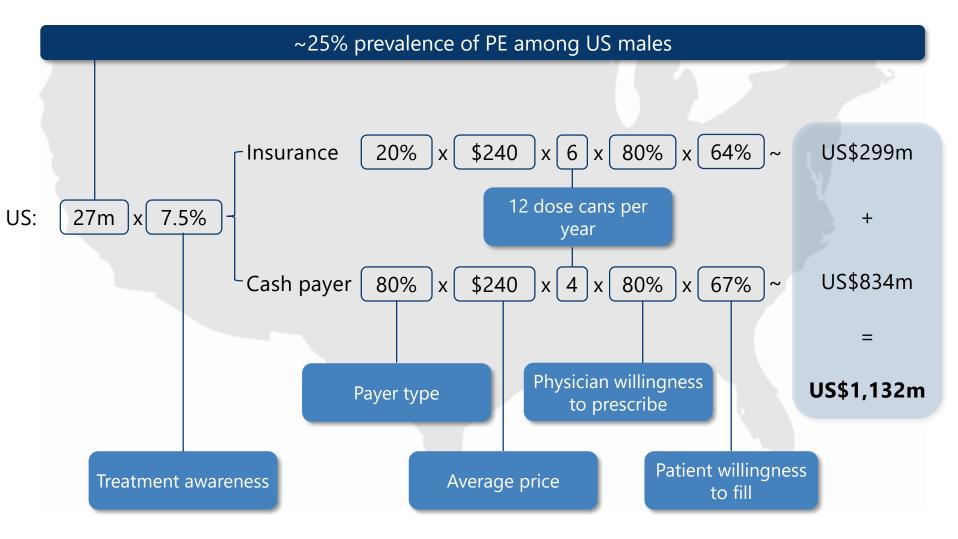
### **Global PE market**

- There are <u>no</u> FDA approved therapies in the US for the treatment of PE
  - Fortacin<sup>™</sup> commenced clinical trials in the US in December 2018 in order to seek FDA approval
- There is one approved therapy for PE in addition to Fortacin<sup>™</sup> in Europe, being Priligy (an SSRI)
- Global addressable patient population of approximately 216 million
- Estimated peak annual sales of US\$2.1 billion
- Licensing agreements <u>signed</u> with i) Shangahi Fosun Pharma subsidiary Wanbang Pharma for PRC, ii) Recordati for Europe, Russia, CIS, Turkey and certain countries of N. Africa, and iii) Orient EuroPharma for HK, Macau, Taiwan, Singapore and other S E Asian countries





### Attractive pricing and sales potential in the US









- Shanghai Fosun is a leading healthcare group in China with a market cap of circa \$8.8 billion with over \$2.7 billion in revenue, fully integrated specialty pharmaceutical company with full clinical and regulatory affairs capability
- Focus: cardiovascular, anti-tumor central nervous systems, blood systems, metabolism and digestive systems, anti-infection, urological and other treatment fields
- Distribution: unparalleled distribution through SinoPharma, China's number
   1 pharmaceutical and healthcare provider and Wanbang Pharma
- Upfront and Milestones: up to \$38 million
- Royalties: low to high teens
- Territory: China



## Partnering provides the potential to earn significant milestones & royalty income stream...



- Mid-size, public (circa €6.3 billion market cap with over €1.2 billion in revenue), fully integrated specialty pharmaceutical company with a strong specialism in men's health
- Focus: urology diseases, cardiovascular and in treatments for orphan/rare diseases
- Sales force: dedicated field force of specialised medical representatives in the urogenital therapeutic area, allowing it to 'plug-and-play' Fortacin<sup>™</sup> into its sales machine
- Milestones: up to €33 million
- Royalties: mid teens to mid twenties range
- Territories: Europe, Russia, CIS, Turkey and certain countries of N. Africa



## Partnering provides the potential to earn significant milestones & royalty income stream...



- Orient EuroPharma is a multinational pharmaceutical company, whose shares are listed on the Taiwan Security Exchange market.
- Focus: pharmaceutical and oncology medicine, adult and baby nutrition and anti-aging products
- Upfront and Milestones: up to \$1.45 million
- Royalties: low teens on net sales
- Territories: Taiwan, Hong Kong, Macau, Malaysia, Brunei, Philippines, Singapore, Thailand and Vietnam,



# Conclusion

### Conclusion



- A focussed healthcare investment vehicle listed on the main board of the Hong Kong Stock Exchange
- Unique opportunity to participate in a high growth story with the defensive quality of a healthcare investment in a volatile global equity market
- Core product Fortacin<sup>™</sup> is a European Medicines Agency approved treatment for Premature Ejaculation and it has market potential that could be on par with Viagra and Cialis at up to US\$2.1 billion per annum
- Recordati commenced commercial sales in Italy, France, Spain, Germany and Portugal in 2018 with other European markets launching in 2019, tapping into a PE market which affects 1 in 4 men
- Signed licence agreements in December 2018 with i)
   Wanbang Pharma, a 100% owned subsidiary of Shanghai Fosun Pharma, tapping a huge potential market of up to 170 million patients, and ii) Orient EuroPharma for HK, Macau, Taiwan, Singapore and other S E Asian countries
- Dr Michael G Wyllie, the scientist behind Viagra and Fortacin<sup>™</sup> will continue to provide scientific oversight and input on the development of Fortacin<sup>™</sup> and valuate/identify other exciting 'late stage' healthcare investments

- Regent Pacific has a strong track record
- Average cash returns generated over the term of investment of nearly two times on material investment disposals over the last 6.5 years from mid 2009 to 2015
- In the 21 years of financial reporting since IPO, returned US\$298 million to shareholders (US\$239.3 million in dividends and US\$59.6 million in share buy-backs)

Regent will continue to pursue strategic and value-led investments, and seek to build a late-stage development portfolio in the healthcare and life sciences sector.