



**Regent Pacific Group Limited** 

COMPANY OVERVIEW October 2017

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### **Company Overview**



# 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 approved treatment for Premature Ejaculation that has the potential to be the next Viagra, with market potential of up to US\$3 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 and CEO Jamie Gibson, who collectively own 24.85%\*



\*as at 9 October 2017 \*\*based on our interim results for the period ended 30 June 2017

### **REGENT CAPITALISATION**

Share price*	HK\$0.34
52 week high – low*	HK\$0.248 – HK\$0.730
Total issued share capital*	1,837 million
90 Day Average Daily Volume*	14.08 million
Market cap*	HK\$625 million (US\$80.1 million)
Cash & listed/unlisted securities**	US\$6.22 million
Debt**	Nil

### LTM SHARE PRICE PERFORMANCE\*



### **Regent Pacific Group Board**



#### 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

#### JAYNE SUTCLIFFE Non-Executive Director

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

#### **JULIE OATES**

Independent Non-Executive Director

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

### **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>
- 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>
- The sector has a highly fragmented structure with the top players in each subsector occupying only a small market share, indicating that the market is still in the early stages of development<sup>3</sup>
- There are 47 pharma/biotech companies listed in HK with a combined market cap of US\$45 billion compared to 66 in London with a combined market cap of US\$228 billion<sup>4</sup>
- 43 of the companies in London have a market cap between US\$30 million and US\$750 million, compared to 31 in Hong Kong<sup>4</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

Healthcare Market
 China
 Scarcity

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

# Plethora Solutions

### **FORTACIN™**

- 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
- Marketing approval obtained from the European Medicines Agency (EMA) in November 2013
- Fortacin<sup>™</sup> is out-licensed to Recordati (REC IM) for Europe, Russia, CIS, Turkey and certain countries of North Africa
- Fortacin<sup>™</sup> now available on commercial sale in the UK by way of prescription and expect Fortacin<sup>™</sup> to be available in Europe through our commercial partner Recordati in early 2018
- NDA filing process commenced with FDA, with approval targeted in Q4 '19





"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

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

- Estimated to be greater than erectile dysfunction
- Estimated at 30-45m men in EU and 50m in USA

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

- Off-label use of antidepressants, topical anesthetic creams, monograph
- Priligy (SSRi) associated with 90% discontinuation; only approved in limited EU territories<sup>\*</sup>

### **FORTACIN™** Overview



Therapeutic

- 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



Commercialisation • Out licensed Fortacin<sup>™</sup> to Recordati, a European pharmaceutical group, to commericalise Fortacin<sup>™</sup> in Europe, Russia, CIS, Turkey and certain countries of North Africa

• Fortacin<sup>™</sup> is now on commercial sale by way of prescription in the UK and thereafter, in early 2018, Fortacin<sup>™</sup> will be available in Europe through our commercial partner Recordati

Regulatory

- EMA approval received in November 2013 the first topical Rx approved in the EU for PE
- USA FDA filing process commenced with aim of submitting NDA during Q1/2 '19, followed by 10 month PDUFA with approval expected in Q4 '19



· Appointment of Pharmaserve as our manufacturing partner



- Potential significant market opportunity, of up to US\$3 billion per annum peak sales for US and EU (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



### 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

### 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 mean IELT (minutes) PSD502-PE-002		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



Patients

**Partners** 



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

### Fortacin<sup>™</sup> Rights





- 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 FDA approval for Fortacin<sup>™</sup> in the US, though it could be 5 years if the 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
- Seeking new manufacturing IP protection for US



Pharmaserve North West (PSNW) has been secured as the supply chain and manufacturing development partner for the new 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



### Fortacin<sup>™</sup> US Regulatory Process



### **US Regulatory Process**



### **Key Considerations**

- Priligy not approved by US FDA, but old monographs used
- Clinical studies conducted under Investigational New Drug
  (IND) programme and in full consultation with FDA
- Strong Key Opinion Leader (KOL) support for product

- 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



### **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 and pending FDA approval	Approved in EU	N/A	N/A
Onset Time	Almost immediately	1-3 hours	10 – 60 minutes	20-30 minutes
Side Effects	Excessive numbing (only 4.5% patients)	Nausea, diarrhea, loss of libido, contraindicated with alcohol	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**
# of Rx Scripts	19 million	18 million	16 million	14.8 million
Cialis	US\$1,259,928,704	US\$1,517,928,576	US\$1,762,138,240	US\$2,134,897,408
Viagra	US\$1,419,078,784	US\$1,604,324,864	US\$1,691,691,648	US\$1,907,254,016
Levitra	US\$351,986,272	US\$290,867,648	US\$224,803,952	US\$210,830,416
TOTAL	US\$3,030,993,760	US\$3,413,121,088	US\$3,678,633,840	US\$4,252,981,840
YoY growth		12.6%	7.8%	15.6%

### **Pricing Considerations**



Therapeutic	US\$ Price per usage	US\$ Price per script
Fortacin™ US market <sup>#</sup>	\$20.83 (3 sprays=1 dose)	\$250 (12 doses)
Fortacin™ EU5 market*	\$6.66 to \$10 (3 sprays=1 dose)	\$80 to \$120 (12 doses)
	US: \$34 to \$48 (per dose)	US: \$409 to \$620 (12 doses)
ED Competitors <sup>1</sup>	EU4 (ex-factory): \$3 to \$14 (per dose) France (public price): \$12 to \$18	EU4 (ex-factory): \$36 to \$168 (12 doses)
		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 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



### **Global PE market**

- There are <u>no</u> FDA approved therapies in the US for the treatment of PE
  - Fortacin<sup>™</sup> will shortly commence clinical trials in the US in order to seek FDA approval
- There is one approved therapy for PE in addition to Fortacin™ in Europe
- Global addressable patient population of approximately 108 million
- Estimated peak annual sales of US\$1.7 billion
- Licensing agreement <u>signed</u> with Recordati for Europe, Russia, CIS, Turkey and certain countries of N. Africa
- Licensing agreements in late stage negotiation for RoW, including North America, LATAM, Asia Pacific region, Middle East and Sub-Saharan Africa





### Attractive pricing and sales potential in the US





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



- Mid-size, public (circa €8.1 billion market cap with over €1 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 €41 million
- Royalties: mid teens to mid twenties range
- Territories: Europe, Russia, CIS, Turkey and certain countries of N. Africa



# Other Investments

### The Diabetic Boot Company Limited (DBC)



Regent Pacific has a 22% stake in DBC having invested £2.39 million (US\$3.09 million), excluding Tranche II and III



- In 2015 there were 415 million diabetics globally and this is expected to grow to 642 million by 2040\*
- 15%-25% of all diabetics will suffer from a diabetic foot ulcer at some point in their lifetime<sup>#</sup>
- The Diabetic Boot Company has developed a patent protected and novel Class 2a medical device that is CE marked in Europe and has FDA 510(k) approval in the US ("PulseFlowDF")
- PulseFlowDF is currently being sold to the Veterans Administration in the US which covers ~22 million lives with a budget in excess of US\$70 billion in 2017
- PulseFlowDF offers distinct advantages over current standard therapy by using intermittent plantar compression
- Improves blood flow and oxygenation in the foot to allow the wound to heal faster
- Takes pressure, shear, and friction forces away from the healing ulcer and looks like normal footwear to remove social stigma

- Proximity sensor to monitor patient compliance
- Supplied as a pair to give balanced gait
- Post therapy shoes with good pressure distribution provide added value by helping to prevent future ulcers
- PulseFlowDF<sup>®</sup> will be sold B2B, into targeted markets across the globe, through networks of specialist stocking distributors, in approximately 40 target countries, and sold directly in the US via a wholly owned subsidiary
- During the period ended 30 June 2017, Diabetic Boot commenced commercialisation of PulseFlowDF directly in the US and through distributors in a number of other countries.
- PulseFlowDF® has been well received by doctors and proven to be reliable. In clinical outcomes, patient response has been overwhelmingly positive.

# Pipeline Opportunities

### Viagra/Cialis (PDEi) Failures



### **Current Landscape**

- Global sales for Viagra/Cialis and now generics in excess of US\$3 billion pa.
- Now accepted that <u>almost half</u> of patients receiving Viagra don't' respond (particularly diabetics).
- Arrival of generics has increased number of patients receiving Viagra (and failing to respond).
- Many non responders will respond to intra penile injection of prostaglandins but pain at injection site.
- Approved injection in certain EU countries of Invicorp (VIP+phentolamine) with most non responders responding.
- Sales potential not realised as injection. Regent proprietary delivery technology should result in topically active therapy.
- Fast track to market (out licensing as 505(b)(2)). Could be out-licensed within 2 years.
- Premium pricing as special needs and IP advantage.





### **Commercial Opportunity**

- The major remaining commercial opportunity in sexual health is for treatment of Viagra/Cialis failures. Almost 50% of ED patients, particularly diabetics, fail to respond adequately to PDE inhibitors.
- Many of these can be treated by e.g. prostaglandins (Caverject or Edex)but this involves direct injection into the penis and there is a 30% incidence of pain at the injection site. There is an alternative using a mixture of VIP and phentolamine that is approved in several EU countries but this also involves intra penile injection.
- There is a high probability that Regent proprietary technology similar to that used in Fortacin will lead to the development of a topical delivery formulation of this agent. The track to market or more realistically outlicensing will be relatively fast as 505(b)(2) and there will be premium pricing as therapy for a special needs population. IP protection will be at least 15 years.



# 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 approved treatment for Premature Ejaculation and it has the potential to be the next Viagra in a market that could be worth up to US\$3 billion per annum
- Now available for sale in the UK by way of prescription and expected to launch in Europe in early 2018 by Recordati S.p.A tapping into a PE market which affects 1 in 4 men
- 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' 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 20 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.