



**Regent Pacific Group Limited** 

COMPANY OVERVIEW 25 MARCH 2017 Dr Mike Wyllie



HK Stock Code 0575 HK

Strong shareholder base, supported by Chairman James Mellon and CEO Jamie Gibson, who collectively own 26.27%\*



\*as at 13<sup>th</sup> March 2017 \*\*based on our interim results for the six months ended 30<sup>th</sup> June 2016

#### **REGENT CAPITALISATION**

Share price*	•••••	HK\$0.52
52 week high – low*	•••••	HK\$0.84 – HK\$0.20
Total issued share ca	pital*	1,737 million
90 Day Average Daily	Volume*	61.7m
Market cap*		HK\$903million (US\$116 million)
Cash and listed securities**US\$10.3 million		
Debt**	• • • • • • • • • • • • • • • • • • • •	Nil

#### LTM SHARE PRICE PERFORMANCE\*



#### **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



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

## Plethora Solutions

**Acquisition of Plethora in March 2016** 

#### Transaction

- Regent Pacific acquired 100% of Plethora in March 2016 in a share-forshare deal that valued Plethora at US\$157 million on a fully diluted basis
- 13.9 billion shares issued as consideration on 9 March 2016
- Dr. Michael G Wyllie, the scientist behind Viagra and Fortacin<sup>™</sup>, joins Regent Pacific management as Chief Scientific Officer of Plethora and will join the board as an executive director at a later date

#### 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
- 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, in 2017, expect Fortacin<sup>™</sup> to be available in Europe through our commercial partner Recordati
- NDA filing process commenced with FDA, with approval targeted in O4 '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\*



#### 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

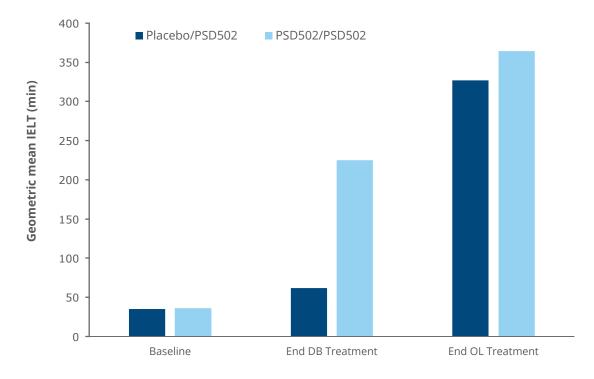
#### Eutectic mixture

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



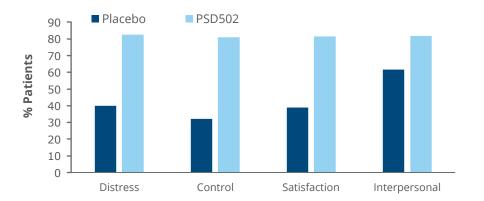


### Significant increase in ejaculatory latency obtained with Fortacin<sup>™</sup> over placebo



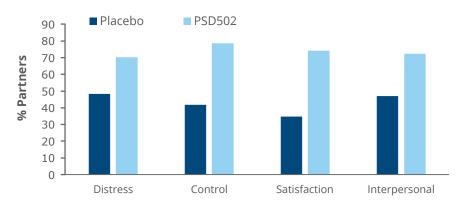
- 3 month double-blind phase: Patients randomised to receive either Fortacin<sup>™</sup> or placebo
- 9 month open-label phase: All patients on Fortacin<sup>™</sup> treatment
- DB Placebo/ OL Fortacin<sup>™</sup> group geometric mean IELT values were shown to gradually increase towards the values of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

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



#### Patients

Partners





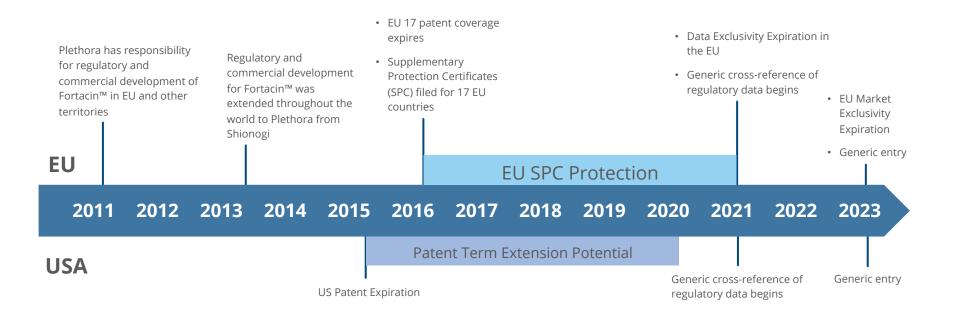
- 4 item questionnaire validated in subjects with PE\*
- Separate patient and partner questionnaires
- Each question answered on a 5-point scale
  - Personal distress related to ejaculation
  - Perceived control over ejaculation
  - Satisfaction with sexual intercourse
  - Interpersonal difficulty related 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



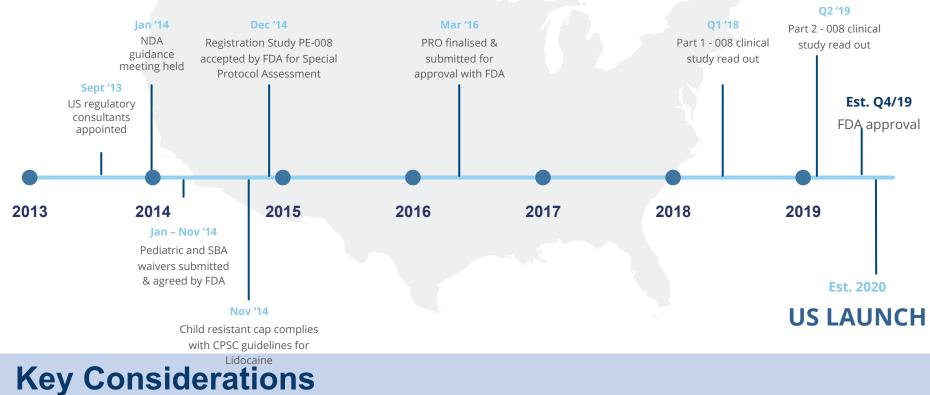


- In September 2014, Plethora acquired the remaining rights to Fortacin<sup>™</sup> for US\$25 million resulting in Plethora owning 100% of the rights to Fortacin<sup>™</sup> on a global basis
- European patent covers the formulation of any or all mixtures of local anaesthetics in hydrofluorocarbon propellants (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

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



#### **US Regulatory Process**



- 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**



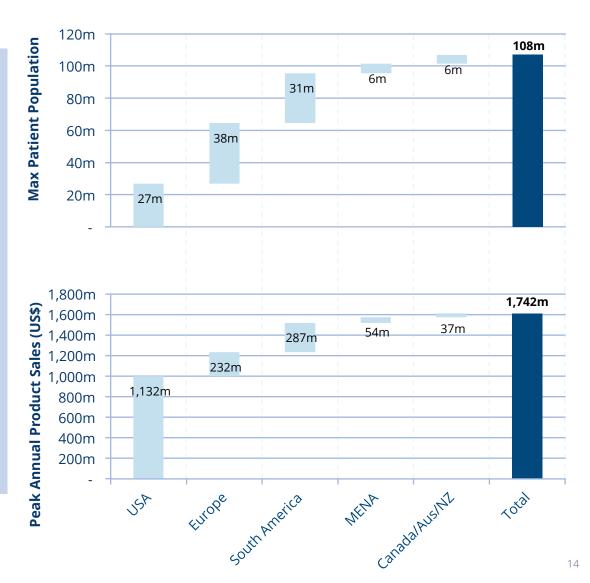
Therapeutic	US\$ Price per usage	US\$ Price per script
Fortacin™ US market <sup>#</sup>	\$20.83 (3 sprays=1 dose)	\$250 (12 doses)
Fortacin™ EU5 market*	\$6.66 to \$10 (3 sprays=1 dose)	\$80 to \$120 (12 doses)
ED Competitors <sup>1</sup>	US: \$34 to \$48 (per dose) EU4 (ex-factory): \$3 to \$14 (per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





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



- Mid-size, public (circa €5.3 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 €46 million
- Royalties: mid teens to mid twenties range
- Territories: Europe, Russia, CIS, Turkey and certain countries of N. Africa



## Other Investments

# Pipeline Opportunities



#### **Current Landscape**

- Global sales for Viagra/Cialis and now generics in excess of \$3billion 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 505b2). Could be out-licensed within 2years.
- 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 out-licensing 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



- 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 2017 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 17.5 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 buybacks)

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.