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# Our Strengths & Ambitions

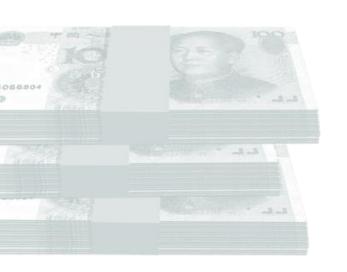
- A focussed healthcare investment vehicle listed on the main board of Hong Kong Stock Exchange
- Strong opportunistic management team and proven transaction track record having returned over US\$298 million to shareholders since listing in May 1997
- Average cash returns generated over the term of investment of nearly two times on material investment disposals over the last 6.5 years
- Our stated strategy is to transform our portfolio to healthcare by being acquisitive with Plethora take-over being the first
- Our core product is PSD502®, a European approved treatment for Premature Ejaculation and it has the potential to be the next Viagra – the market could be worth up to US\$3 billion per annum
- Hong Kong listing 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

#### **Financial Information**



#### HK Stock Code 0575 HK

Strong shareholder base, supported by Co-Chairman Jim Mellon and CEO Jamie Gibson, who collectively own 27%\*



#### REGENT CAPITALISATION

Share mid-price (9 Mar '16)	HK\$0.08
52 week high – low	HK\$0.245 – HK\$0.062
Total issued share capital	
Market cap*	HK\$1,390m (US\$179m)
Cash and cash equivalent*	US\$10m
Debt*	Nil

#### LTM SHARE PRICE PERFORMANCE\*



\*as at 9 March 2016

#### **Our Board**



#### **JAMES MELLON**

Non-Executive Co-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

#### STEPHEN DATTELS

Non-Executive Co-Chairman

 Experienced senior mining executive who has helped to form and finance a number of mining ventures

#### **JAMIE GIBSON**

Chief Executive Officer

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

#### **SAM SEARLE**

Independent Non-Executive Director

Over 30 years' experience in the investment management industry

#### **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

#### **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**

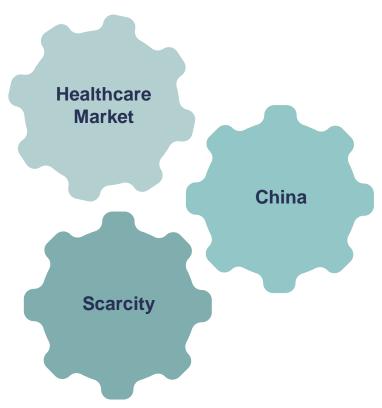
Non-Executive Director

 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 \$357 billion in 2011 to \$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\$45bn compared to 66 in London with a combined market cap of US\$228bn<sup>4</sup>
- 43 of the companies in London have a market cap between \$30m and \$750m, 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 with strong execution all drive value

## **Plethora Solutions**

#### **Acquisition of Plethora in March 2016**



### **Transaction**

- Regent Pacific acquired 100% of Plethora in March 2016 in a share-for-share deal that valued Plethora at US\$157m on a fully diluted basis
- 13.9 billion shares issued as consideration on 10 March 2016
- Dr. Michael G Wyllie, the scientist behind Viagra and PSD502<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

### PSD502®

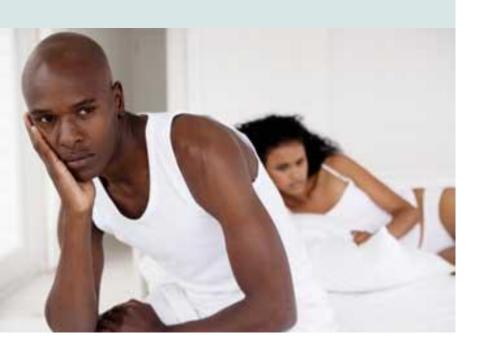
- Plethora's lead asset is PSD502<sup>®</sup>, a novel Rx topical treatment for premature ejaculation, with potential to go mass market
- Focus is on bringing PSD502<sup>®</sup> to market through strategic commercial partners
- Marketing approval obtained from the European Medicines Agency (EMA) in November 2013
- PSD502<sup>®</sup> is out-licensed to Recordati (REC IM) for Europe, Russia, CIS, Turkey and certain countries of N. Africa
- NDA filing process commenced with FDA, with submission targeted by end of Q2 '17



#### **Premature Ejaculation (PE)**



"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 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\*

#### **PSD502® 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 PSD502® to Recordati, a European pharmaceutical group, to commericalize PSD502® in Europe, Russia, CIS, Turkey and certain countries of North Africa

#### 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 Q2 '17 incorporating new can size, followed by 10 month PDUFA with approval expected in Q2 '18

#### **Partnerships**

 Appointment of Pharmaserve and Catalent as development and manufacturing partners, leading to development and manufacturing of new reduced dose canister

#### **Market Potential**

- Potential significant market opportunity, of up to \$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 over PSD502<sup>®</sup>
- Commercial marketing partners are to gain support from KOLs for PSD502® to become 1st line on treatment guidelines where applicable



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

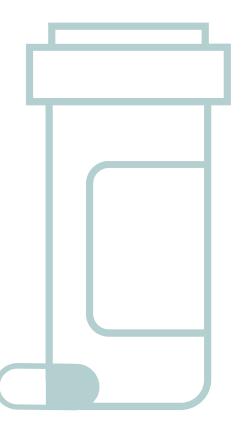
- Mean IELT\* at baseline was 0.5 min rising to 3.2 min at week 12
- 87% of patients considered as responders
- Excellent tolerability in ~ 23,500 doses delivered with no significant safety issues
- Can be used with and without condom

#### 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

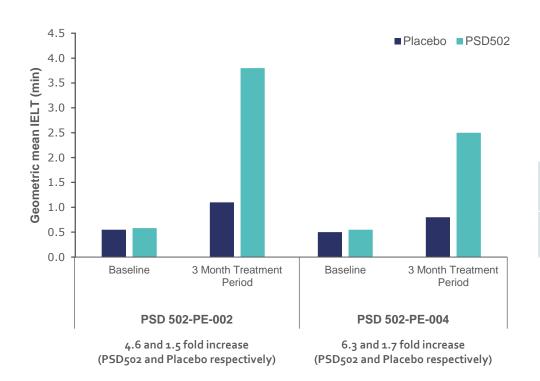
#### **Eutectic mixture**

- 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 PSD502® over placebo

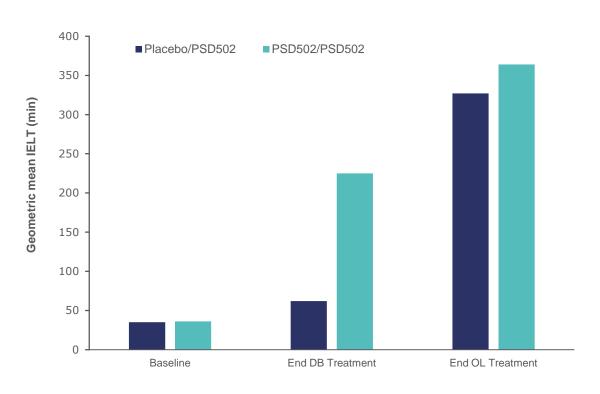


	Geometric mean IELT (min) PSD 502-PE-002		Geometric mean IELT (min) PSD 502-PE-004	
	Placebo	PSD 502	Placebo	PSD 502
Baseline	0.53	0.56	0.58	0.60
3 Months Rx	0.80	2.61	1.07	3.85

#### **Effect is Durable in Long-Term**



# Significant increase in ejaculatory latency obtained with PSD502® over placebo

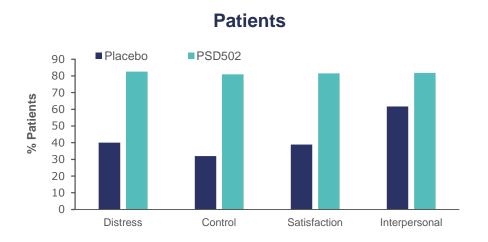


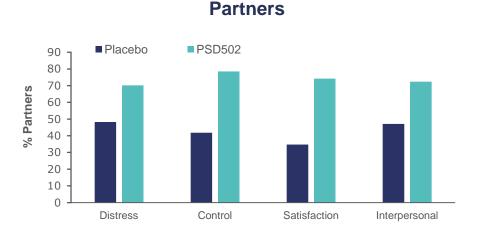
- 3 month double-blind phase: Patients randomised to receive either PSD502® or placebo
- 9 month open-label phase: All patients on PSD502® treatment
- DB Placebo/ OL PSD 502® group geometric mean IELT values were shown to gradually increase towards the values of the DB PSD502®/ OL PSD502® group

#### **Premature Ejaculation Profile (PEP)**



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





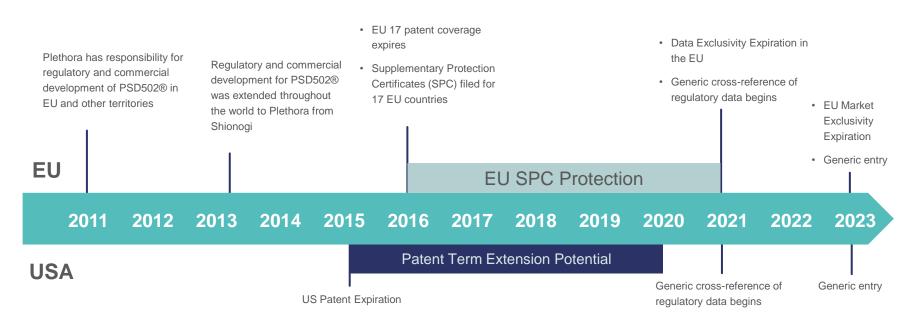
- 4 item questionnaire validated in subjects with PE\*
- Separate patient and partner questionnaires
- Each question answered on a 5-point scale
  - Personal distress related to ejaculation
  - Perceived control over ejaculation
  - Satisfaction with sexual intercourse
  - Interpersonal difficulty related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

More patients and partners using PSD502® 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

#### PSD502® Rights





- In September 2014, Plethora acquired the remaining rights to PSD502® for US\$25M resulting in Plethora owning 100% of the rights to PSD502® 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 PSD502<sup>®</sup> in the US, though it could be 5 years if the FDA treats PSD502<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

#### **Manufacturing Partners Pharmaserve NW**



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



#### **Timeline**

 PSNW is undertaking the work required for generating data suitable for EU license variation and for inclusion in the initial submission of the NDA with the US FDA

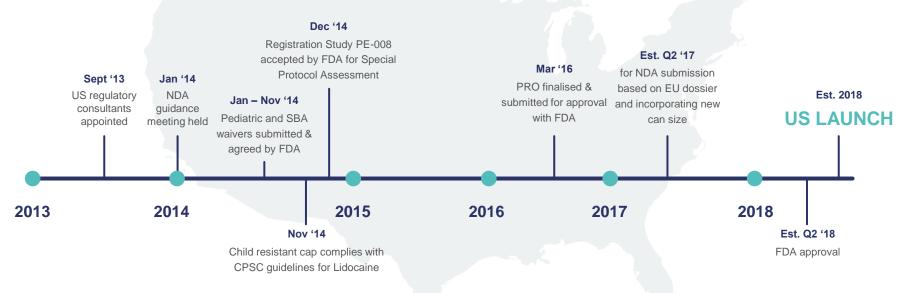


#### Experience

- 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 obtaining GMP certification from the FDA



### **US Regulatory Process**



### **Key Considerations**

- Priligy not approved by US FDA, but old monographs used
- Clinical studies conducted under IND and in full consultation with FDA
- Strong Key Opinion Leader (KOL) support for product
- · Requesting FDA advisory committee meeting

- 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

### **Male Sexual Function Landscape**



18

### **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	19M	18M	16M	14.8M
Cialis	\$1,259,928,704	\$1,517,928,576	\$1,762,138,240	\$2,134,897,408
Viagra	\$1,419,078,784	\$1,604,324,864	\$1,691,691,648	\$1,907,254,016
Levitra	\$351,986,272	\$290,867,648	\$224,803,952	\$210,830,416
TOTAL	\$3,030,993,760	\$3,413,121,088	\$3,678,633,840	\$4,252,981,840
YoY growth		12.6%	7.8%	15.6%

\*Source: MME, April 2016, \*\*MME, March 2016

#### **Pricing Considerations**



Therapeutic	Price per usage	Price per script
PSD502® US market#	US\$16.67 (3 sprays=1 dose)	US\$100 (6 doses)
PSD502® EU5 market*	EU5 US\$6.66 to \$10 (3 sprays=1 dose)	EU5 US\$40 to US\$60 (6 doses)
ED Competitors <sup>1</sup>	US: US\$34 to US\$46 (per dose)  EU4 (ex-factory): US\$3 to US\$14 (per dose)  France (public price): US\$9 to US\$14	US: US\$205 to US\$275 (6 doses)  EU4 (ex-factory): US\$15 to US\$82 (6 doses)  France (public price): US\$56 to US\$82
Priligy <sup>®2</sup>	EU3 Ex-Factory (Germany, Italy & Spain): US\$4 to US\$7 France public price US\$32 to US\$46	EU3 Ex-Factory (Germany, Italy & Spain): US\$25 to US\$43 France public price: US\$194 to US\$277

- Price corridor for ED drugs is fairly wide amongst EU4 (average ranges from US\$17 to US\$82)
- Germany is 12% to 25% above the EU4 average for most of the ED drugs
- UK and Italy are commonly (2% to 41%) below the EU4 average

- Plethora expect healthcare authorities will not reimburse PSD502<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 PSD502® to become 1st line on treatment guidelines where applicable

#### **Business Strategy – Potential to Go Mass Market**





# Partnering provides the potential to earn significant milestone & royalty capital...



- Mid-size, public (circa €4.5bn 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' PSD502™ into its sales machine
- Milestones: up to €46M
- Royalties: mid teens to mid twenties range
- Territories: Europe, Russia, CIS, Turkey and certain countries of N. Africa
- Negotiating other licensing agreements for RoW, including North America,
   LATAM, Asia Pacific region, Middle East and Sub-Saharan Africa



# Other Investments

#### The Diabetic Boot Company



Regent Pacific holds 17% of shares in The Diabetic Boot Company having invested £1.2 million (US\$1.9m) in May 2015



- Diabetes had 415 million sufferers in 2015 and 642 million people are expected to be diabetic by 2040\*
- 15%-25% of all diabetics will suffer from diabetic foot ulcers at some point in their lifetime#
- The Diabetic Boot Company has developed a patent protected and novel Class 2/ IIa medical device that is CE marked and has FDA 510(k) approval ("PulseFlowDF")
- PulseFlowDF offers distinct advantages over current standard therapy
- Improves blood flows and oxygenation in the foot to allow the wound to heal faster

- Takes pressure, shear, and friction forces away from the healing ulcer
- Looks like normal footwear to remove social stigma
- Records patient wear rates to improve patient compliance
- Supplied as a pair to give balanced gait
- Superb after therapy "added value" by helping to prevent future ulcers
- PulseFlowDF® 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 USA via a wholly owned subsidiary

<sup>\*</sup>International Diabetes Federation/idf.org,

<sup>#</sup>GE Rieber et al; Epidemiology of diabetic foot ulcers and amputations. The evidence for diabetes care London John Wiley & Sons 2002

# Conclusion

#### Conclusion



- A focussed healthcare investment vehicle listed on the main board of 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 PSD502® 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 \$3bn p.a.
- Commercialization of PSD502® expected to launch initially in EU by Recordati in the latter half of 2016 –tapping into a PE market which affects 1 in 4 men
- Michael G Wyllie, the scientist behind Viagra and PSD502<sup>®</sup>, will continue to provide scientific oversight and input on the development of PSD502<sup>®</sup> and evaluate/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
- In the 17.5 years of financial reporting since IPO, returned US\$298 million to shareholders (US\$239.3mn in dividends and US\$59.6mn 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.