

PIC/S GMP 藥廠

PBF 寶齡富錦生技[®]
Panion & BF Biotech Inc.

A photograph of two runners on a paved path. In the foreground, the lower half of a person in black leggings and white sneakers is visible, running towards the right. In the background, a person in a white t-shirt and black shorts is running away from the camera. The path is surrounded by green grass and trees under a clear blue sky.

活力自信·健康美麗

健康帶來活力、美麗創造自信·寶齡·綻放美好生命

Company Overview

October 2014

Disclaimer

This document contains forward looking statements that relate to the Company's prospective financial condition, results of operations and its business plan, strategies, forecasts, prospective competitive position and growth opportunities. This document also contains forward looking statements that relate to the market, financial and regulatory environments in which the Company plans to operate, the plans and objectives of the Company's management and various other matters. These forward looking statements are identifiable by words such as "anticipate", "estimate", "project", "plan", "intend", "expect", "believe", "forecast" and similar expressions used in this document. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which could cause the Company's actual results, performance or achievements to differ from those expressed in, or implied by, such statements. These statements reflect the Company's current beliefs and are based upon information available as of the date of the announcement. Prospective investors should be aware that these statements are estimates, reflecting only the judgment of the Company's management and prospective investors should not rely on any forward looking statements.

Highlights

- ✓ **Lead product Nephoxil (Pharmaceutical Grade Ferric Citrate)**
 - US NDA approved in Sep 2014
 - Japan NDA approved in Jan 2014
- ✓ **The only dual effects phosphate binder on the market:**
 - Serum Phosphate control + Anemia Amelioration
- ✓ **Global phosphate binder's market >US\$ 1.5 B**
- ✓ **Clear Product Life Extension Pathway**

THE COMPANY

PANION & BF BIOTECH INC.

Company profile



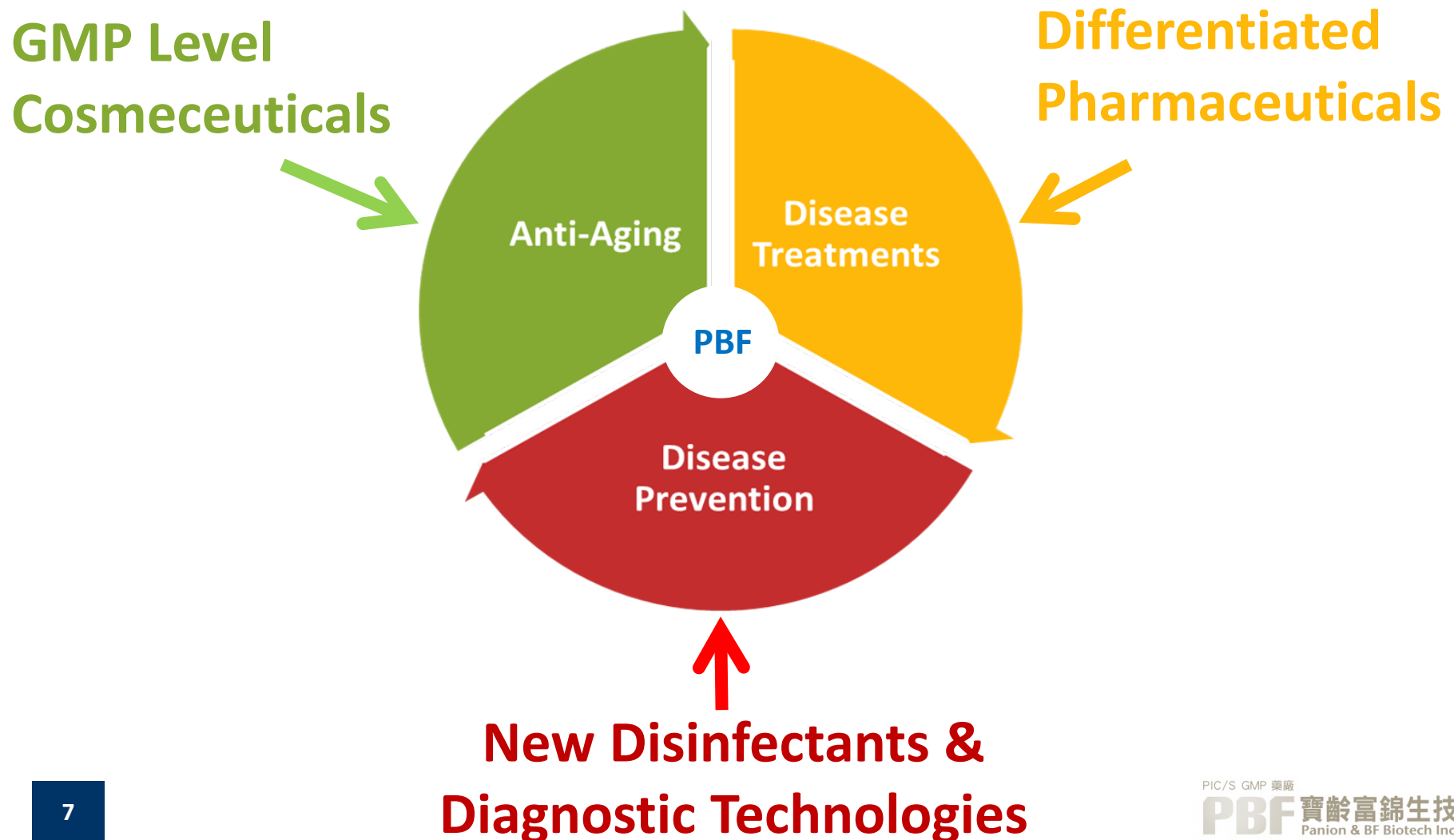
- **Founded in 1976.**
- **Currently traded on Taiwan OTC Emerging Market (Ticker: 1760)**
- **Shares outstanding : 48M**
- **2013 Revenue : US\$ 28.56M (yoy 27%)**
- **Current number of Employees : 275**

Panion & BF Biotech Inc.



- **The only double GMP manufacturer in Taiwan**
 - ▣ Pharmaceutical: PIC/S GMP
 - ▣ Cosmetic GMP
- **Our Capabilities:**
 - ▣ Integrated system for marketing, sales and distribution
 - ▣ Strong Research & Development
 - ▣ Established Nephrology Network for New Product Development
 - ▣ Global Quality Standard for Manufacturing

Key Market Area and Product Portfolio



Our Vision and Philosophy

- **Vision** : To enhance people's quality of life through innovation and technology
- **Philosophy** : Care, Share and Health



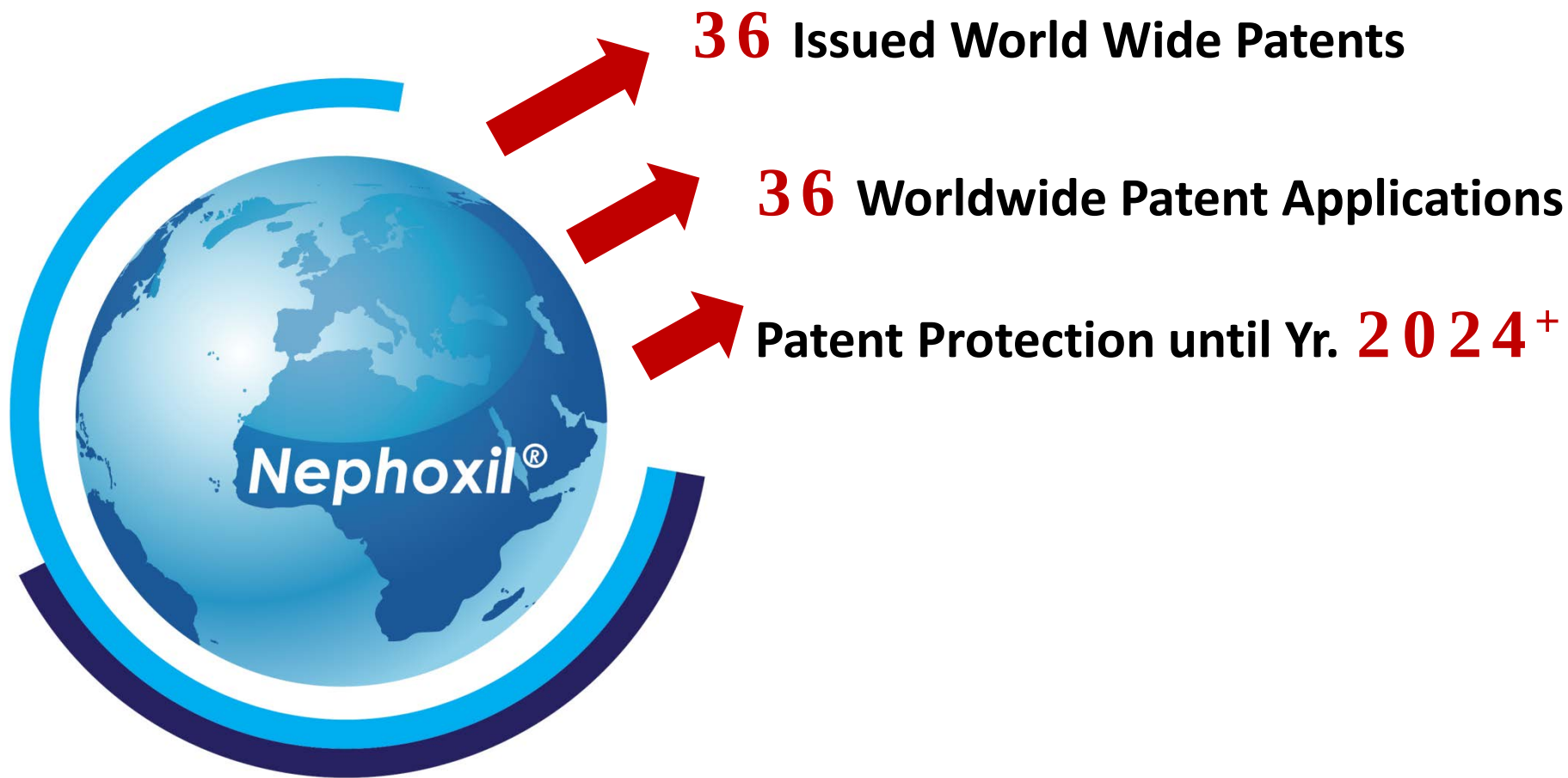
NEPHOXIL[®] INTRODUCTION

Nephoxil® Overview

- **New Generation Iron Based Phosphate Binder:**
 - ▣ Indicated for the treatment for Hyperphosphatemia in ESRD
 - ▣ Extra benefit to anemia treatment
 - ▣ Clear pharmacoeconomic benefit
 - ▣ Expanding to NDD-CKD (Approved in Japan)
- **Global NDA Status:**
 - ▣ Japan: **NDA Approved**
 - ▣ USA: **NDA Approved**
 - ▣ Taiwan: Late stage NDA review
 - ▣ EU: Late stage NDA review



Global IP Portfolio



CKD & HYPERPHOSPHATEMIA MARKET

Chronic Kidney Disease (CKD)

- Global healthcare problem:
 - ▣ 10%~11% prevalence rate worldwide
- 5 Stages classification by severity. The End Stage Renal Disease (ESRD, CKD 5) requires dialysis for survival

Stage	Description	GFR (ml/min/ 1.73 m2)	Prevalence N (1000s)	%
1	Kidney Damage with Normal or ↑ GFR	≥ 90	5,900	3.3
2	Kidney Damage with Mild ↓ GFR	60-89	5,300	3.0
3	Moderate ↓ GFR	30-59	7,600	4.3
4	Severe ↓ GFR	15-29	400	0.2
5	Kidney Failure	<15 or dialysis	300	0.2

Source: Stages 1-4 from NHANES III (1988-1994). Stage 5 from USRDS (1998)

Facts about ESRD & Hyperphosphatemia

- **Current world wide ESRD population: 2.5million patients with average growth rate of 7%. *Source: Fresenius ESRD Patients in 2013***
- **>80% of all ESRD patients suffer from Hyperphosphatemia (elevation of serum phosphorus)**
- **Phosphate binders is the major treatment**
 - **Bind to dietary phosphorus and effectively reduce the absorption into blood.**

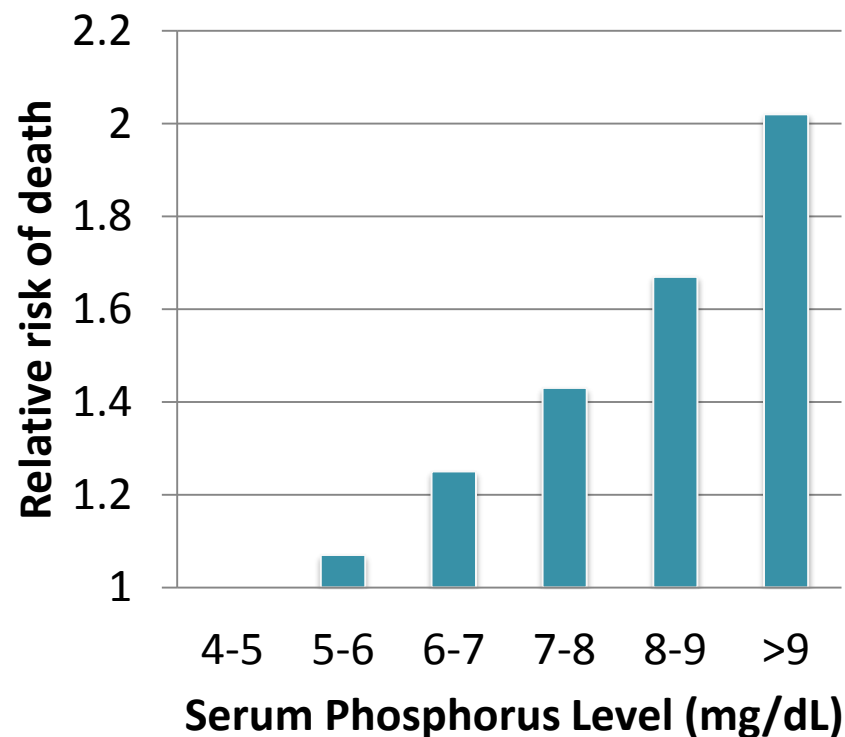
Why controlling serum phosphorus?

- If not treated,
Hyperphosphatemia can lead to:

- ▣ Hyperparathyroidism
- ▣ Bone disorder
- ▣ Systemic calcification
- ▣ **Cardio-vascular calcification**
- ▣ **Increased relative risk of death**

50% dialysis patients will die
from cardiovascular disease
instead of kidney failure.

Source: *J Am Soc Nephrol* 15: 2208–2218, 2004



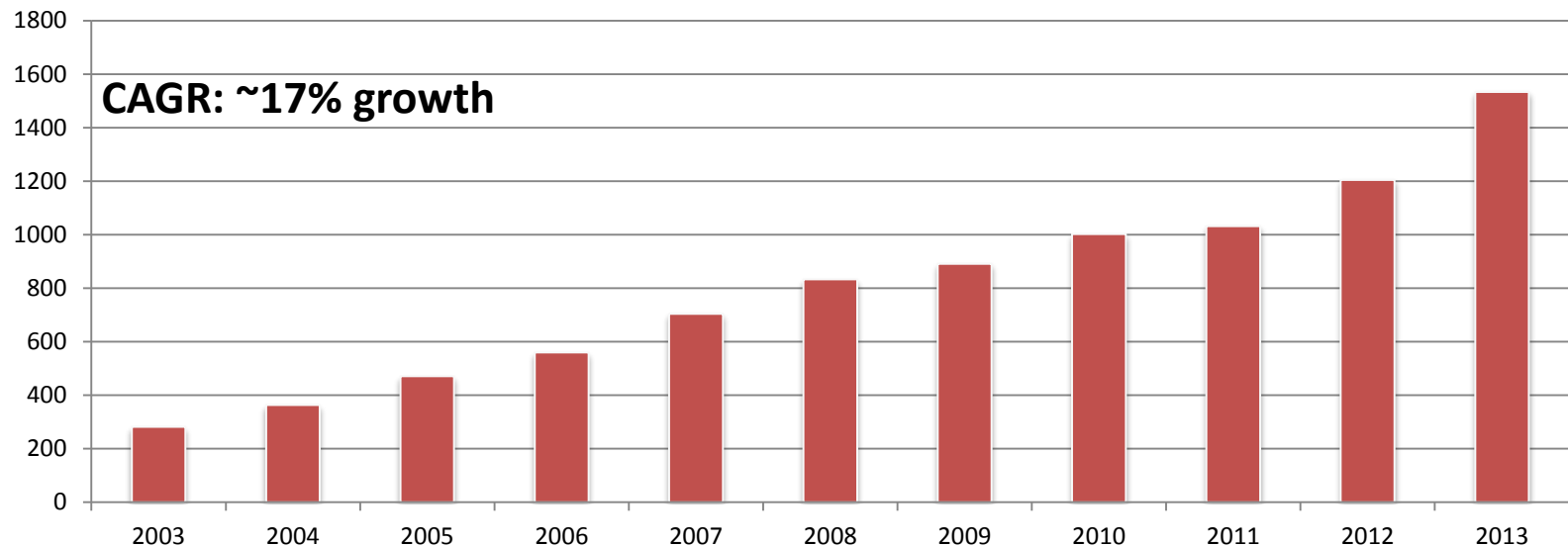
Current treatments and Issues

Product	Provider	Disadvantages	Annual cost*
Aluminum	Generic	Aluminum toxicity: Accumulation in bone, neural and brain system.	Low
Calcium	Generic	Hypercalcemia is related to promoting vascular calcification	Low
Sevelamer	Sanofi/ Genzym	Adverse GI effects; higher cost. Weak binding, high pill burden	US\$5,500
Lanthanum	Shire	Lanthanum accumulation in bone and other tissues; high cost Big pill: Chewable tablet 750~1000 mg	US\$7,000
Sucroferric oxyhydroxide	Vifor Pharma	Big pill: Chewable tablet 2500 mg No effect on Iron or anemia score	Not yet available

* M.Tonelli. *N Engl J Med* 2010;362:1312-24

Phosphate Binder's Market exceeded US\$1.5 billion in 2013

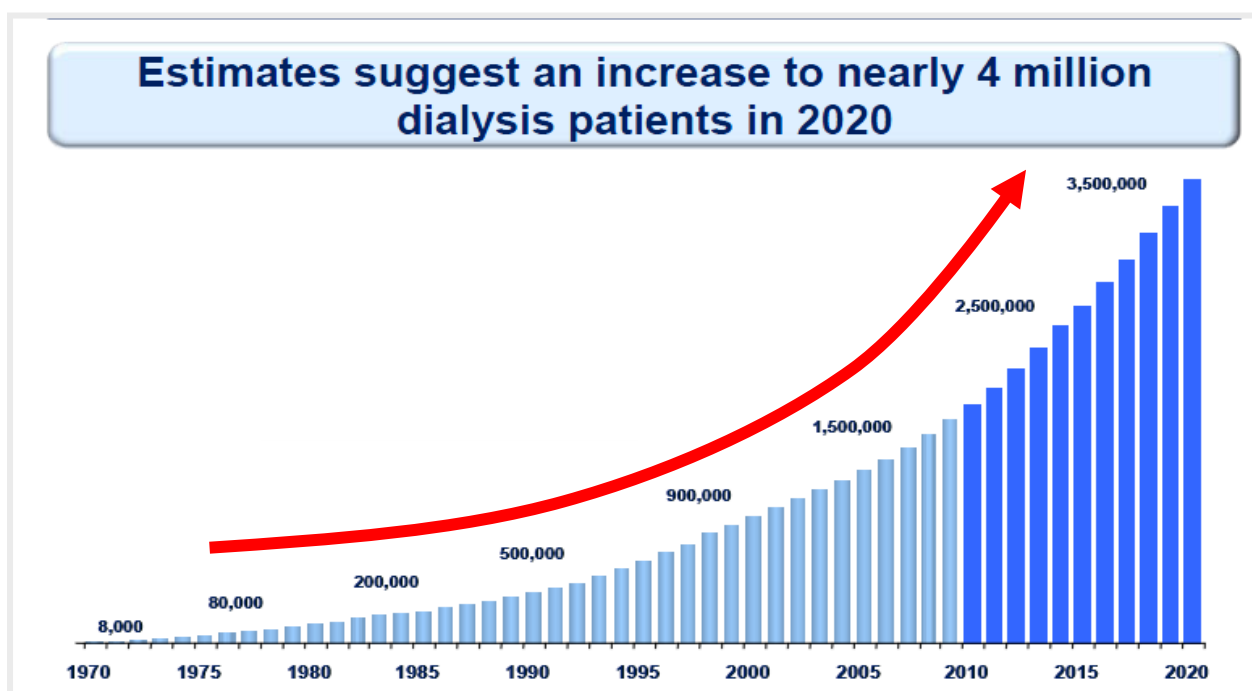
Non-Calcium Phosphate binder market



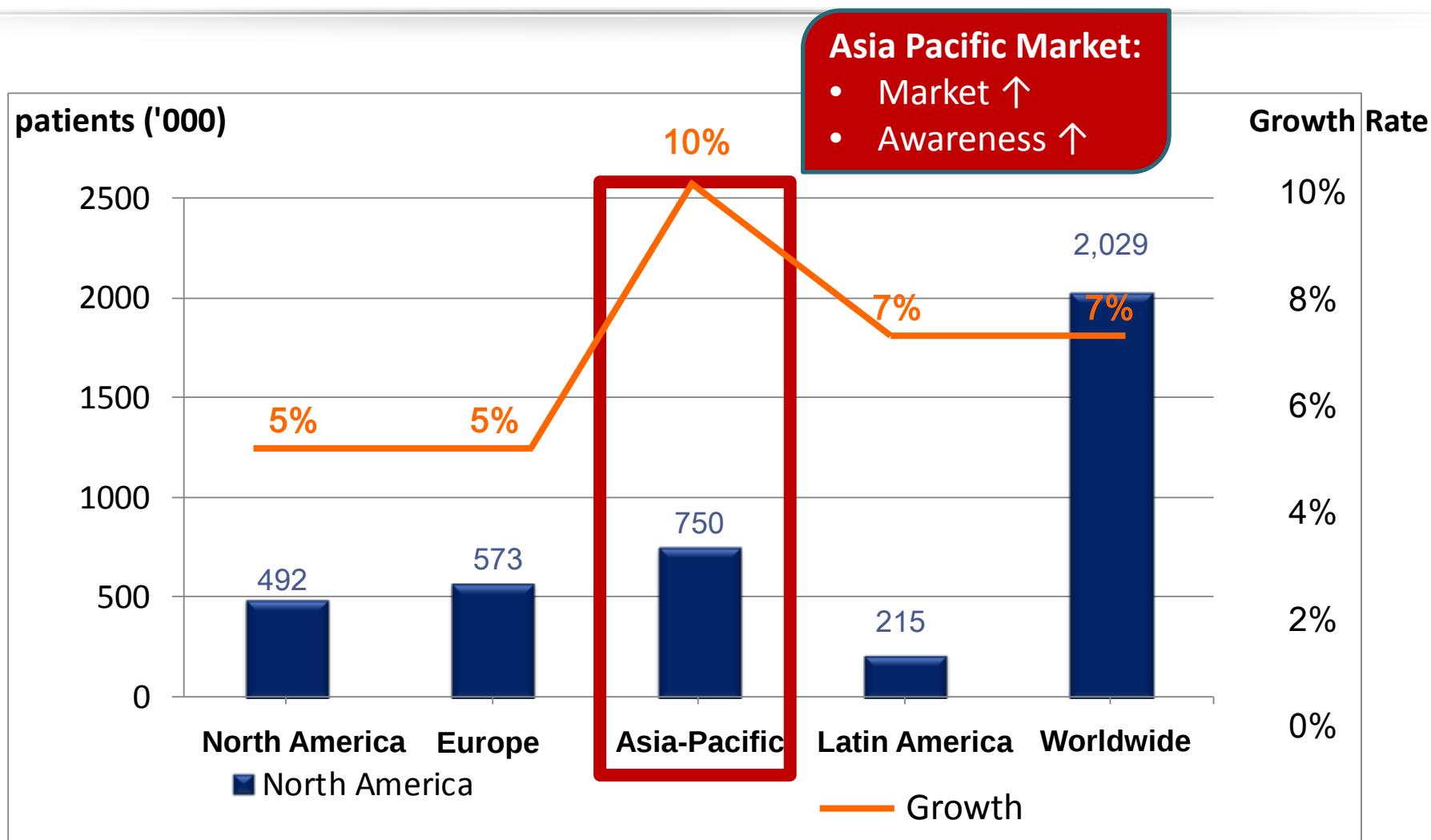
Unit: Million USD											
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Sevelamer	\$282	\$364	\$417	\$515	\$603	\$678	\$707	\$698	\$685	\$803	\$1,030
Lanthanum			\$54	\$45	\$102	\$155	\$184	\$304	\$348	\$402	\$503
Sub-total	\$281.7	\$363.7	\$471.0	\$559.9	\$704.9	\$833.1	\$891.0	\$1,002	\$1,032	\$1,204	\$1,533

Rapid growth of dialysis population

- More than 2.5M dialysis patients worldwide in 2013, and estimated to exceed 4M+ in 2020.
- Key factors: Ageing population, Global epidemic of diabetes and cardiovascular disease



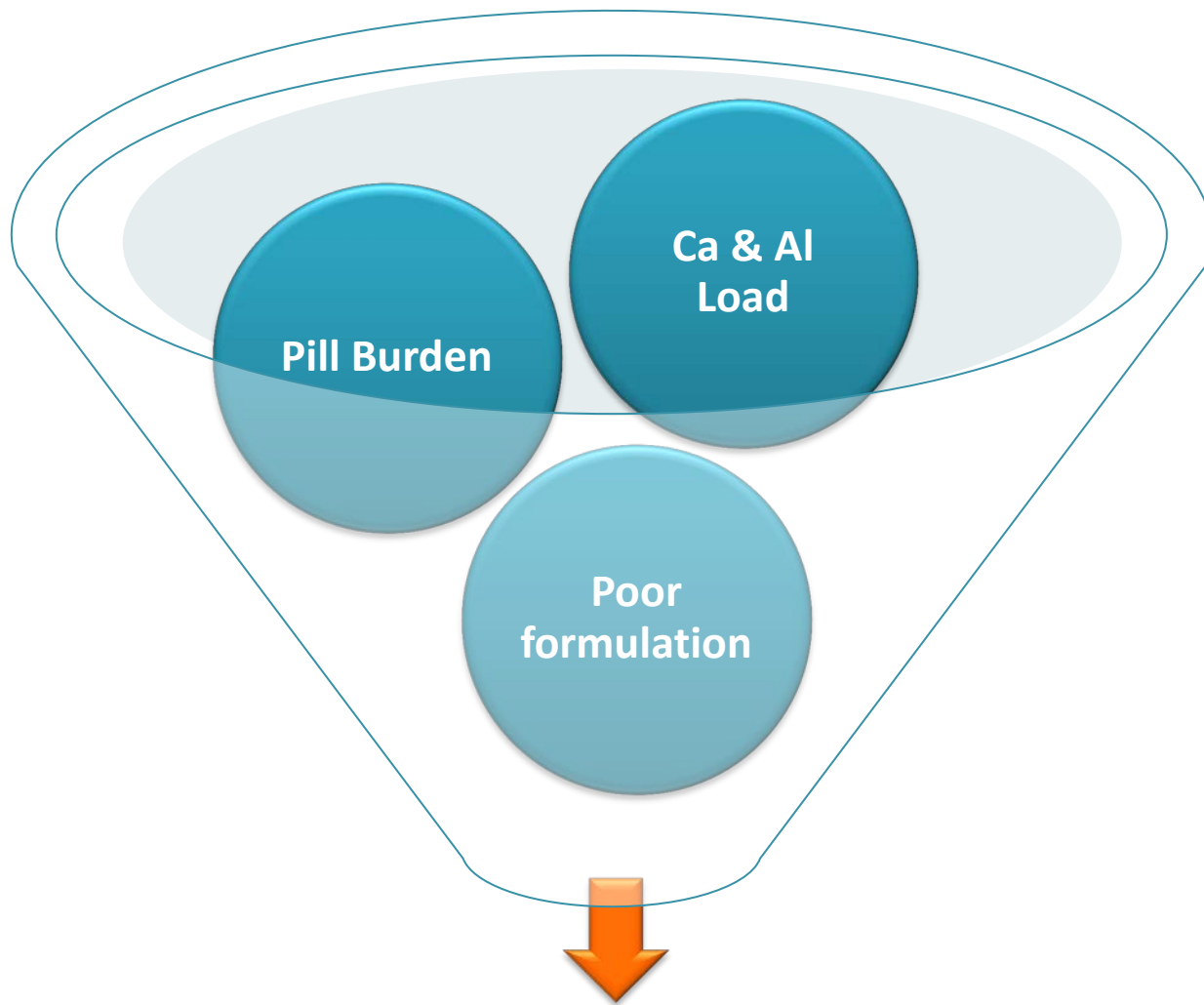
Strong growth in Asia Pacific Region





NEPHOXIL®

Unmet Medical Needs for a Better Phosphate Binder





Nephoxil[®]

New Iron Base Phosphate binder

- Iron: An essential element to human
- No concerns of Ca/Al/La accumulation
- Good Clinical Safety & Tolerability
- Compact Formulation
- Effective control of serum phosphate
Meet K/DOQI Guideline: Serum Phosphorus < 5.5 mg/dl
- Improve Iron & Anemia Parameters



Pharmaceutical Grade
Ferric Citrate Coordination
Complex

Reduced use of IV Iron & ESA

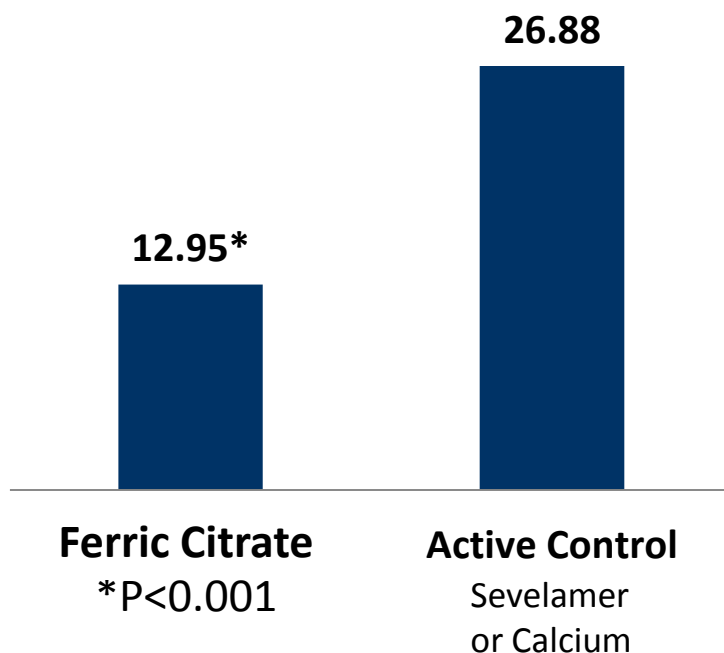
Long term study

**Data from J Am Soc Nephrol 26, 2014 (Ref 3)*

Reduced IV Iron use

by **52%**

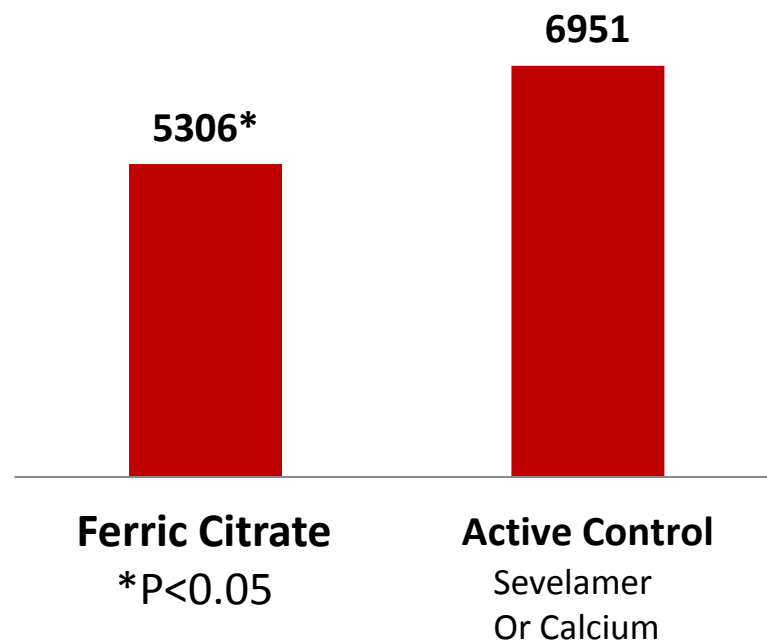
IV Iron use (mg/week)



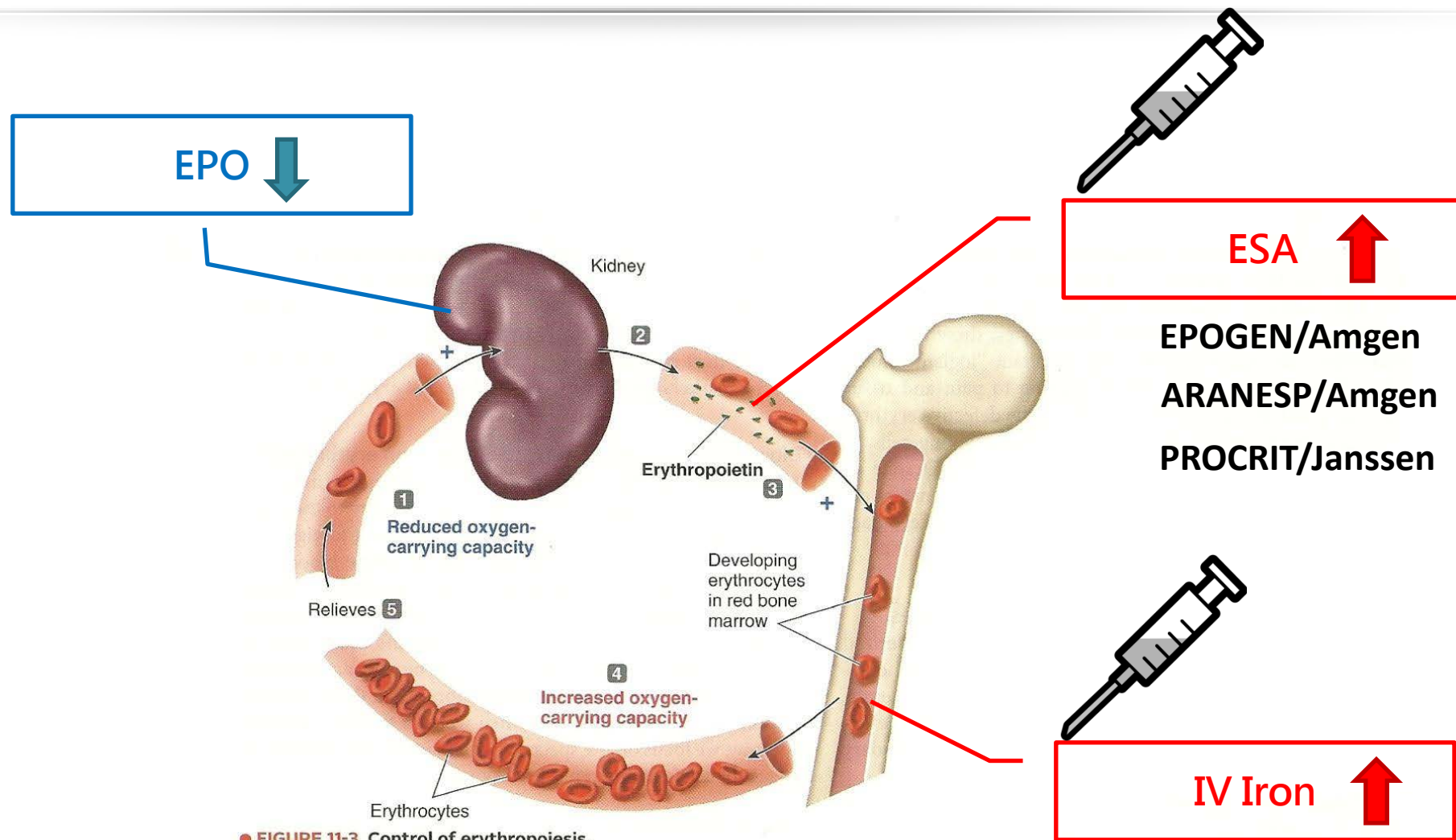
Reduced ESA use

by **24%**

ESA Use (units/week)



Anemia is one of the most common complications in CKD population



Significant Pharmacoeconomic Savings

**Data from Int J Nephrol Renovasc Dis. 2014 May 20;7:191-201 (Ref 5)*

- If ferric citrate usage reduced ESA utilization by 20% and IV iron by 40%, potential savings on US Healthcare spending can be:

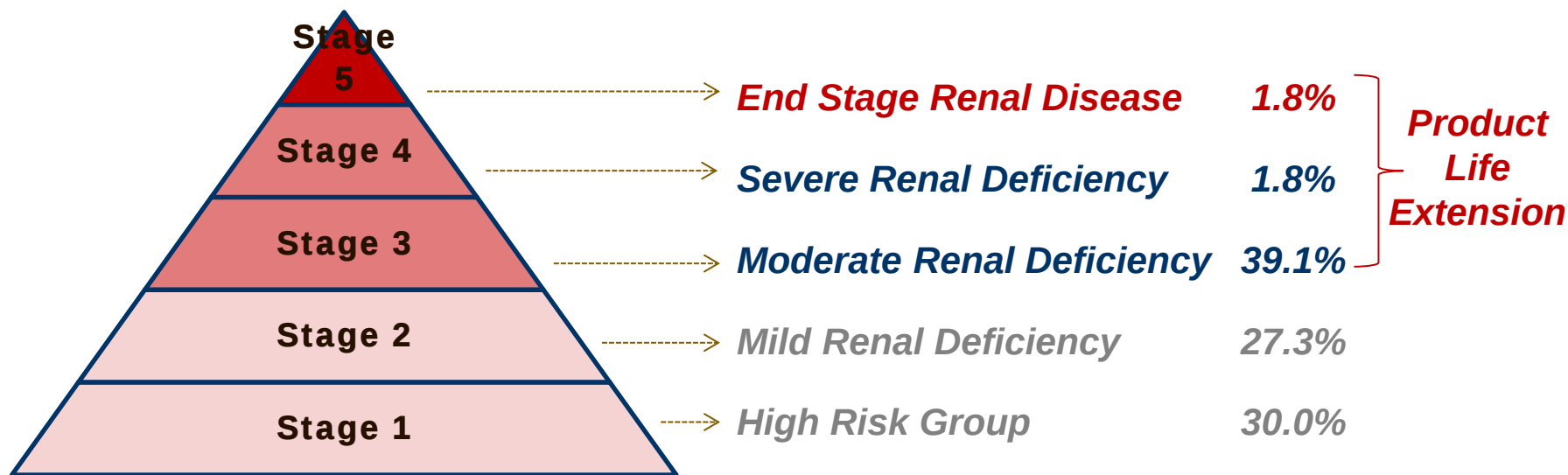
	ESA+IV Iron annual cost (Based on Centers for Medicare and Medicaid Services)	ESA+IV Iron annual cost (Based on actual usage)
Before Ferric Citrate	US\$ 5.127 Billion	US\$ 3.981 Billion
After Ferric citrate	US\$ 4.038 Billion (21.2% saving)	US\$ 3.111 Billion (21.8% saving)

*Determined by Monte Carlo analysis

Nephoxil®

Product Life Cycle Management

- Extension to Non-Dialysis Dependent CKD patients (CKD Stage 3~5).
- NDD-CKD approved in Japan in 2014 (Ref 4)
- New indications (Patent filed)



CKD 5 Stages

Source: Stages 1-4 from NHANES III (1988-1994). Stage 5 from USRDS (1998)

Nephoxil® Global Development

