

中化合成生技股份有限公司

Chunghwa Chemical Synthesis & Biotech Co., Ltd.



C C S B

Chih-Ping Yang, Ph.D.

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First Securities Investment Forum 2016Q2

Disclaimer



- **CCSB's presentation contains forward-looking statements subject to significant risks and uncertainties. Actual results may differ materially from those contained in the forward-looking statements.**
- **The forward-looking statements in this release reflect the current belief of CCSB's as of the date of this release, we undertake no obligation to update these forward-looking statements for new information, future events or otherwise.**

Agenda



Business Overview

Major Products & Market Outline

Strength & Opportunity

Financial Highlights

Q & A

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Our Vision



**Expertise the launch of
innovative high-quality API
to pharmaceutical
industries globally**

Business Development Strategic



➤ Product Portfolio

- Equally Develop Synthetic & Biotech Products.
- Focus on Microbial Fermentation Products.
- Partake in New Drug Development and Contract Manufacturing.

➤ Market Layout

- Key Point Markets: NAFTA, Europe and Japan.
- Export > 96%.

High Level of Quality



➤ Authority inspected GMP Products List

Year	Authorities	Products	Year	Authorities	Products	
2006	TFDA	PDE	2012	German Authority TFDA	PVTS FCZ, MATX, RAPA	
2007	KFDA	MCB		2013	TFDA PMDA KFDA	OLO, RAPA, EVE, CAS FK506 FK506
2008	NIP TFDA	TDP RAPA	2014		FDA	Full Products
2009	German Authority TFDA	PVTS MCB, PVTS		2015	German Authority TFDA Mexico	PVTS, FK506 Full Products CAS
2010	TFDA	FK506, MMF				
2011	USFDA	MMF, FK506/SD20, DEXB				

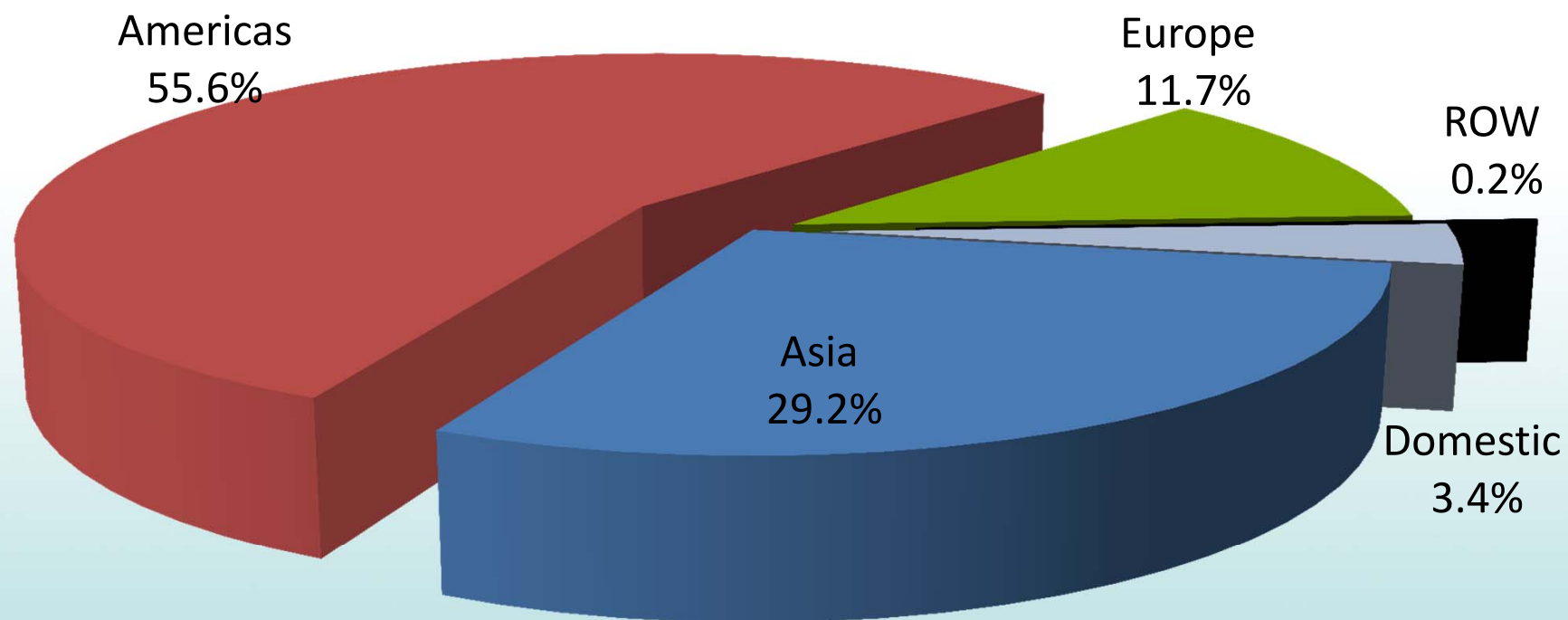
High Level of Quality (cont.)



Customers Inspected Products List

Year	North America	Europe	Asia
2008	MMF, RAPA, PVTS, MCB	PDE	MCTP
2009	MCB, DEXB, FK506-SD20, RAPA		BSF, GGE, PVTS
2010	Rapa, FK506, MCB, PVTS, TDP,	TDP, MCB	MCB, MMF, PVTS
2011	RAPA, PVTS, FCZ, DEXB, MMF, FK506, MCB, FK506-SD20, MTAX, CAS	PVTS, OLO	GGE, FK506
2012	RAPA, DEXB, MCB, MTAX	EPAE, PVTS, MCB, CAS	FCZ, PVTS
2013	TDP, EPAE, PVTS	MCB, MMF, PVTS, EPAE, EVE, FK506	FK506, EPAE, FCZ,
2014	EVE, DEXB, RAPA, MMF, FK506, EPA, MCB,	CAS, OLO, EVE	RAPA, PVTS, EVE, FK506, FKSD, FCZ, MCB, MATX
2015	MCB, MCB USP, DEXB, INGM	OLO, GGE, FK506, MCB,	MCB, FK506,

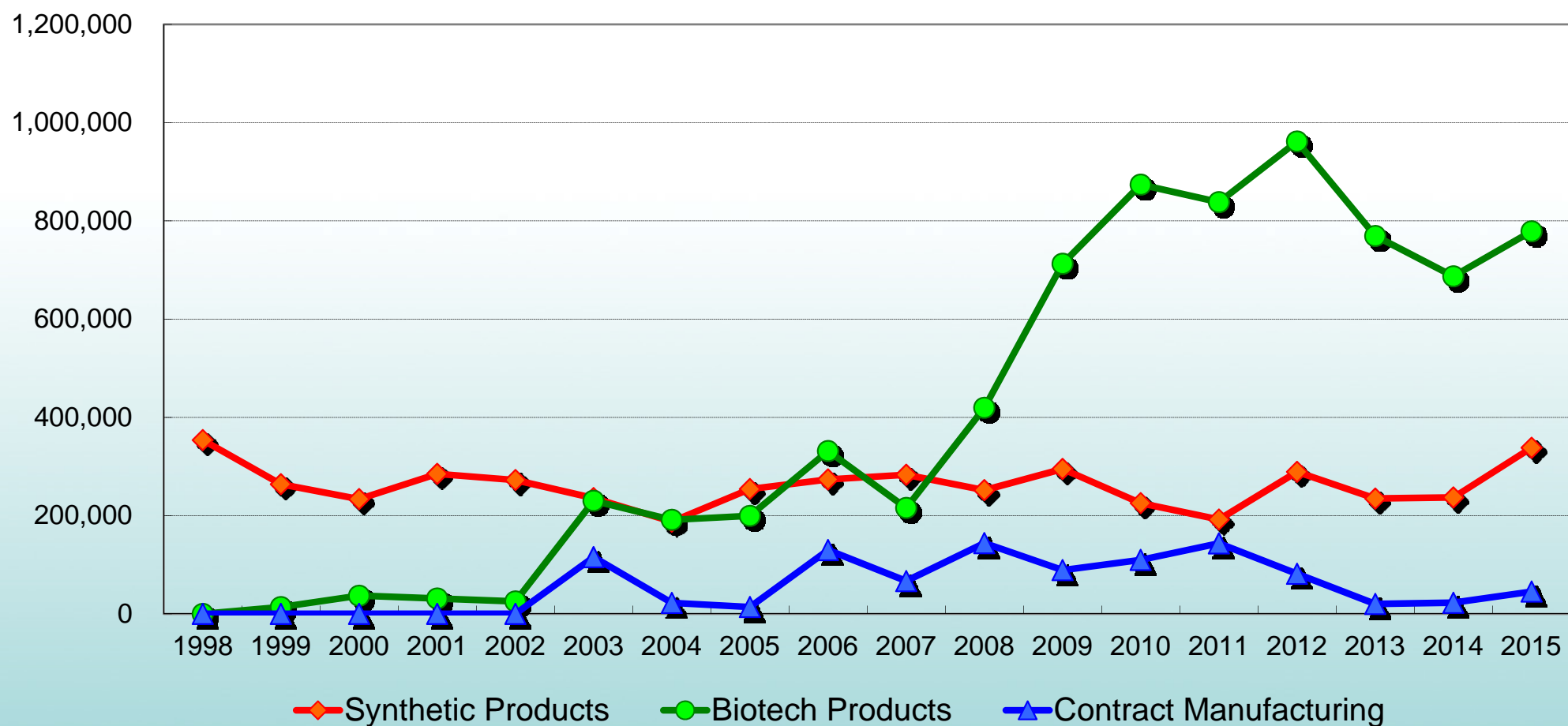
Sales Area in 2015



Revenue Tendency



Unit : NTD Thousands



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Major Products and Indication



➤ Biotech Products

– Immunosuppressant

- Mycophenolate Mofetil (MMF)
- MMF HCl
- Mycophenolate Sodium
- Tacrolimus
- Rapamycin
- Everolimus

– Anti-cancer

- Everolimus
- Ingenol Mebutate

– Antifungal

- Caspofungin
- Micafungin

– Antihyperlipidaemics

- Pravastatin

Major Products and Indication (cont.)



➤ Synthetic Products

– Musculoskeletal Relaxant

- Methocarbamol
- Metaxalone

– Antihypertension

- Trandolapril

– Antihypertension Intermediate

- ZP7

– Anti-cancer

- Carfilzomib

– Anti-triglycerides

- EPA
- Epanova

– Antihistamine

- Dexbrompheniramine
Maleate

New Launched Products



Unit: USD Millions

Name	Complete Data	2015 CCSB API Sales	2015 Global FDF Market	Patent Expiry	Indication
Metaxalone	2013	1.1	262	Expired	Musculoskeletal
Caspofungin Acetate	2013	1.4	533	2013/05	Antifungal
Everolimus	2013	6.8	1,788	2019/09	Anticancer/ Immunosuppressant
Ingenol Mebutate	2015	0.6	99	2018/08	Anticancer
Carfilzomib	2015	0.1	548	2025/04	Anticancer

Source : NewPort (2015 Global FDF Market)

Metaxalone



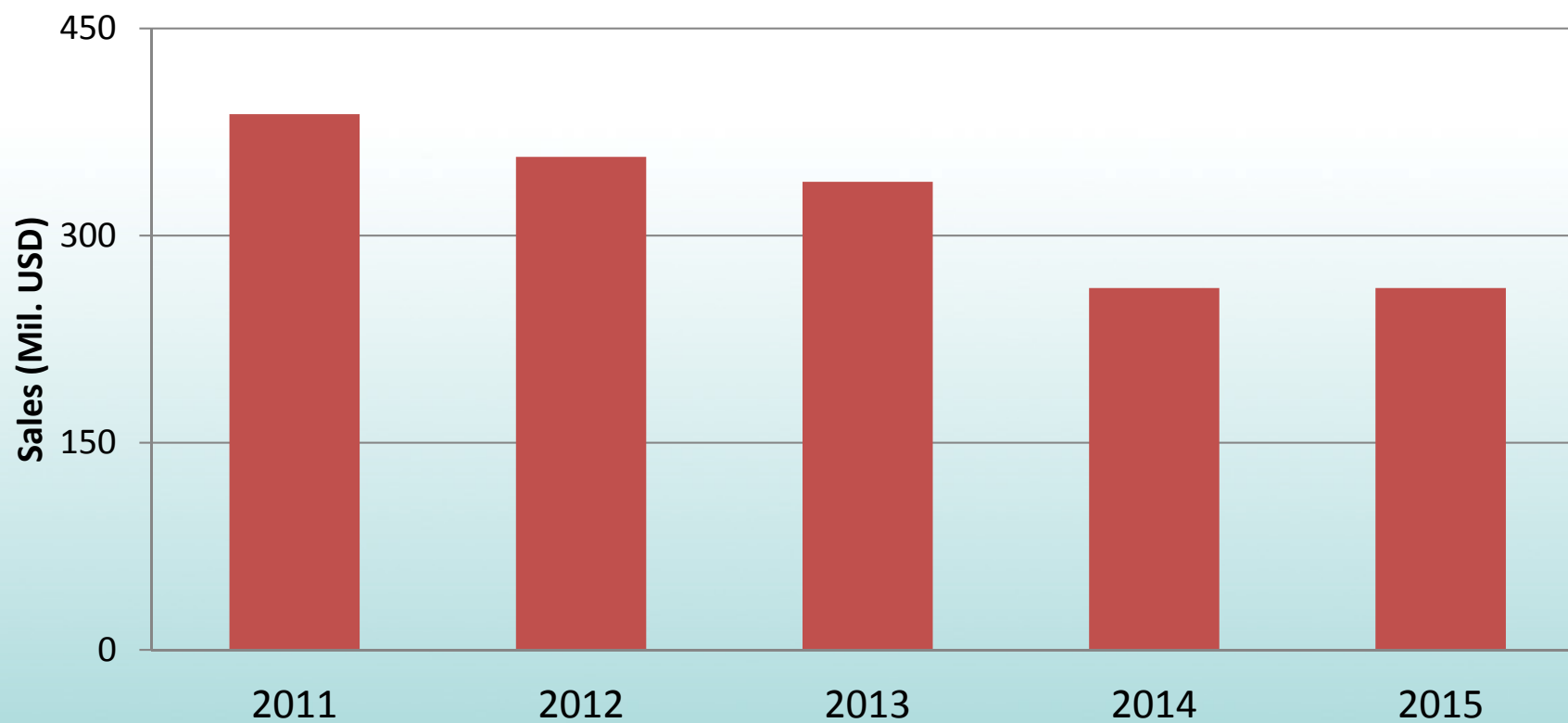
➤ Metaxalone

- **Applicant: King Pharm**
- **Musculoskeletal Relaxant: Skelaxin**
- **indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions.**
- **US 2015 annual sales: 262 Million dollars**

Metaxalone (cont.)



➤ Metaxalone US Sales



Caspofungin Acetate



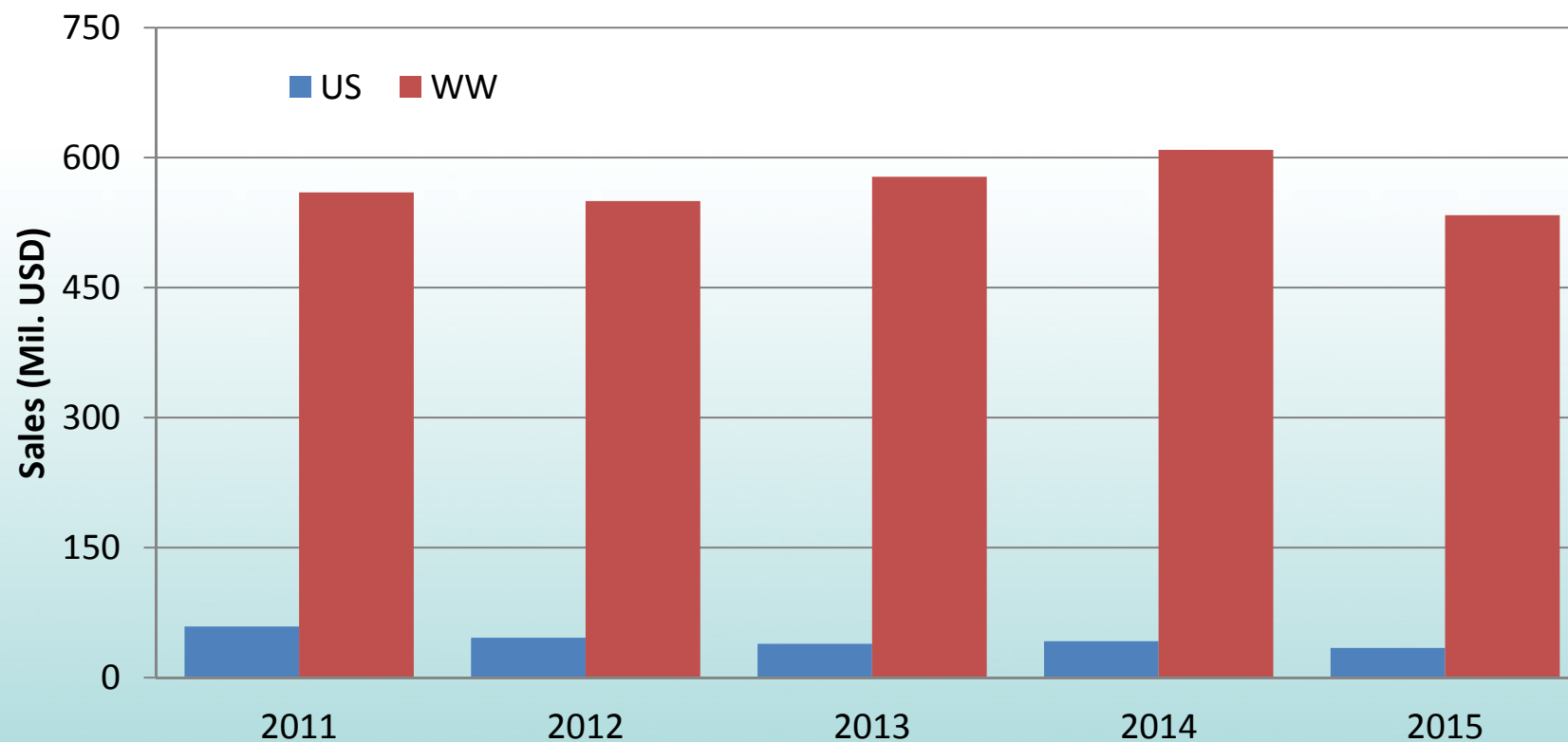
➤ Caspofungin Acetate

- **Applicant : Merck**
- **Antifungal : Cancidas**
- **Indication: Candidemia and the following Candida infections. intra-abdominal abscesses, peritonitis and pleural space infections**
- **Global 2015 annual sales: 550 Million dollars**

Caspofungin Acetate (cont.)



➤ Caspofungin Acetate US/Global Sales



Everolimus



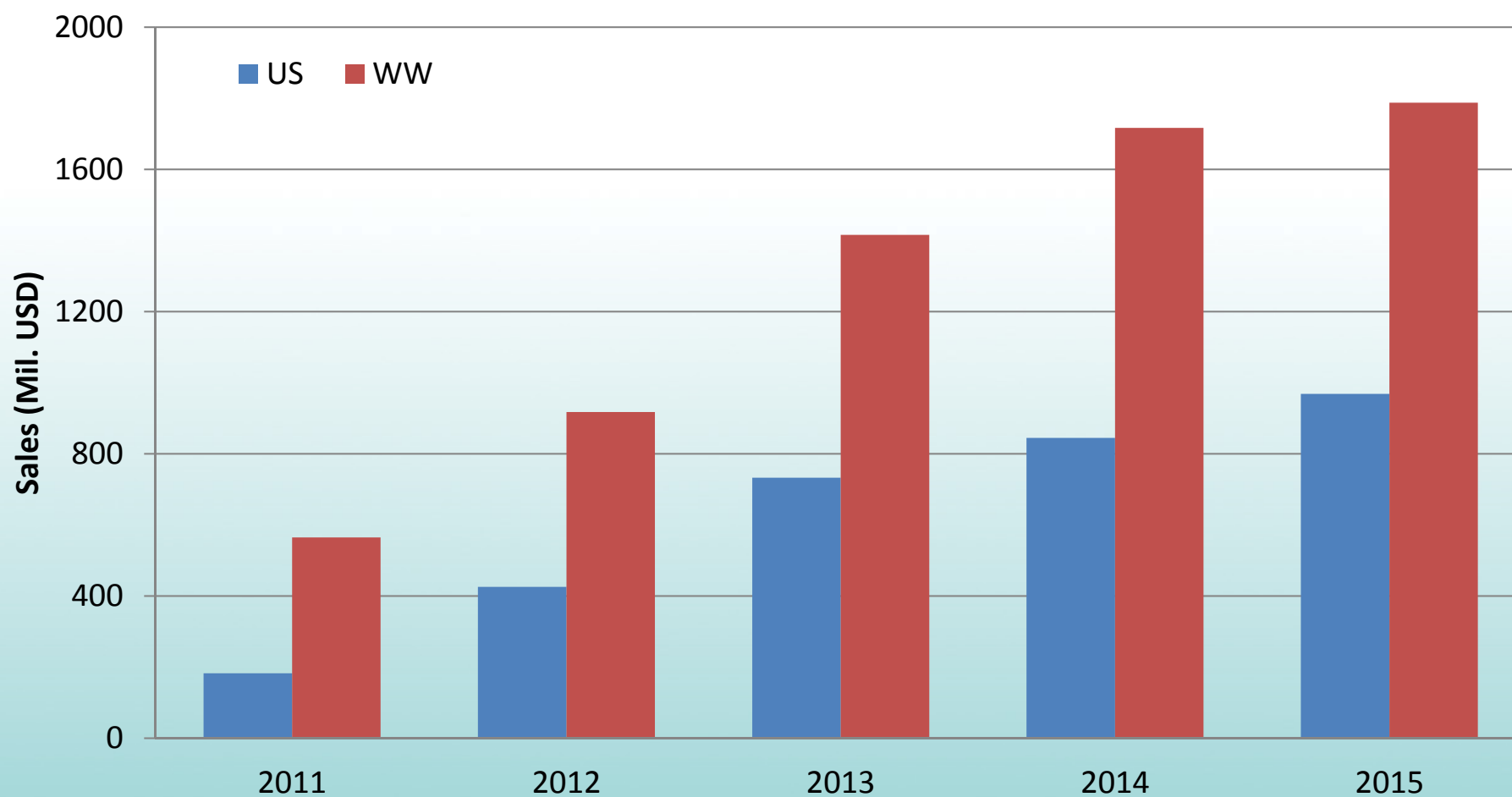
➤ Everolimus

- **Originator : Novartis**
- **Transplant Drugs : Zortress (US); Certican (Europe & other counties).**
- **To prevent transplant rejection (antirejection medicine)in people who have received a kidney or heart transplant.**
- **Anti-Cancer Drug: Afinitor**
- **Approved for pancreatic cancer and kidney cancer treatments.**
- **The efficacy data is being examined by FDA on July 12, 2012 as treatment for breast cancer.**
- **Patent Expiration time : Sep. 2019**
- **Global 2015 annual sales: 1788 Million dollars**

Everolimus (cont.)



➤ Everolimus US/Global Sales



Ingenol Mebutate



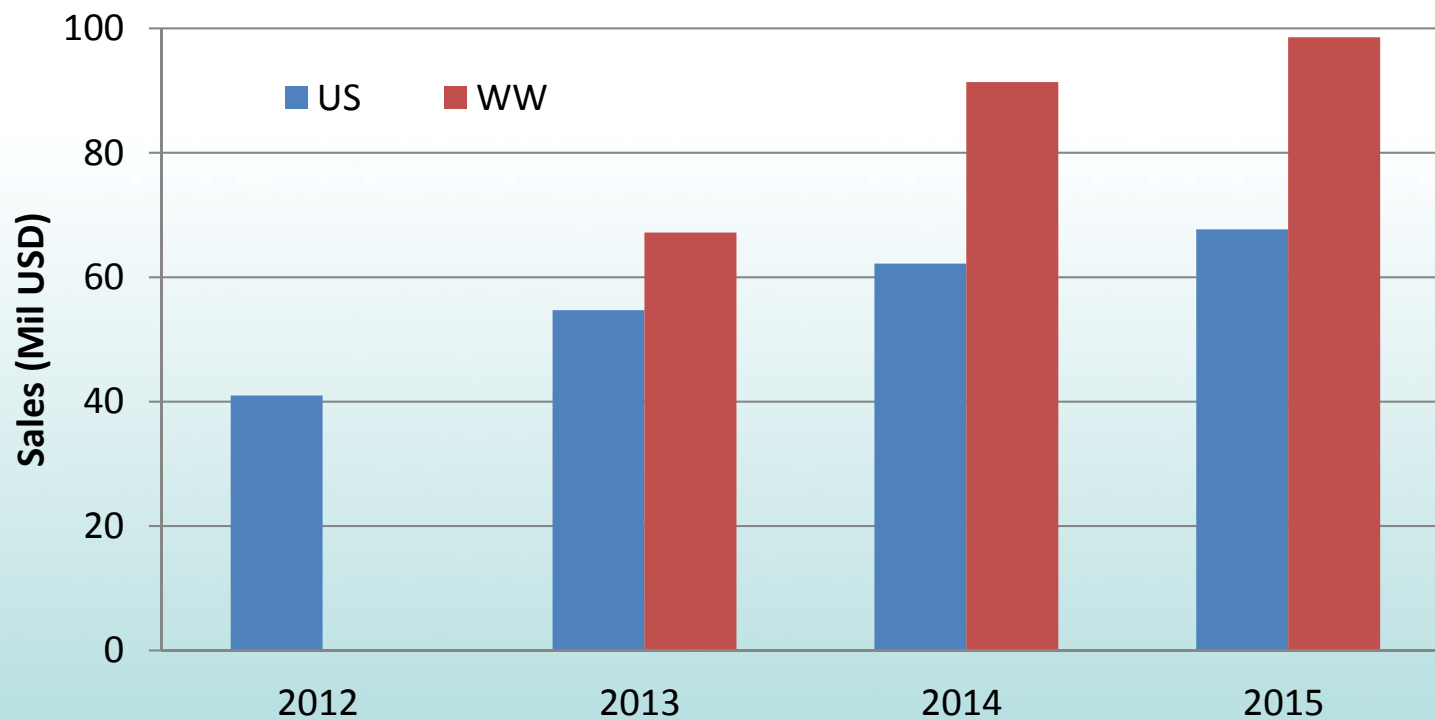
➤ Ingenol Mebutate

- **Applicant : LEO Pharma**
- **Oncology Drug : Picato**
- **Treatment of Actinic Keratosis and inhibit the proliferative activity of Neoplastic Cells.**
- **Extraction from the sap of the plant Euphorbia peplus**
- **Patent Expiration time: Aug. 2018**
- **Global 2015 annual sales: 99 Million dollars**

Ingenol Mebutate (cont.)



➤ Ingenol Mebutate US/Global Sales



Carfilzomib



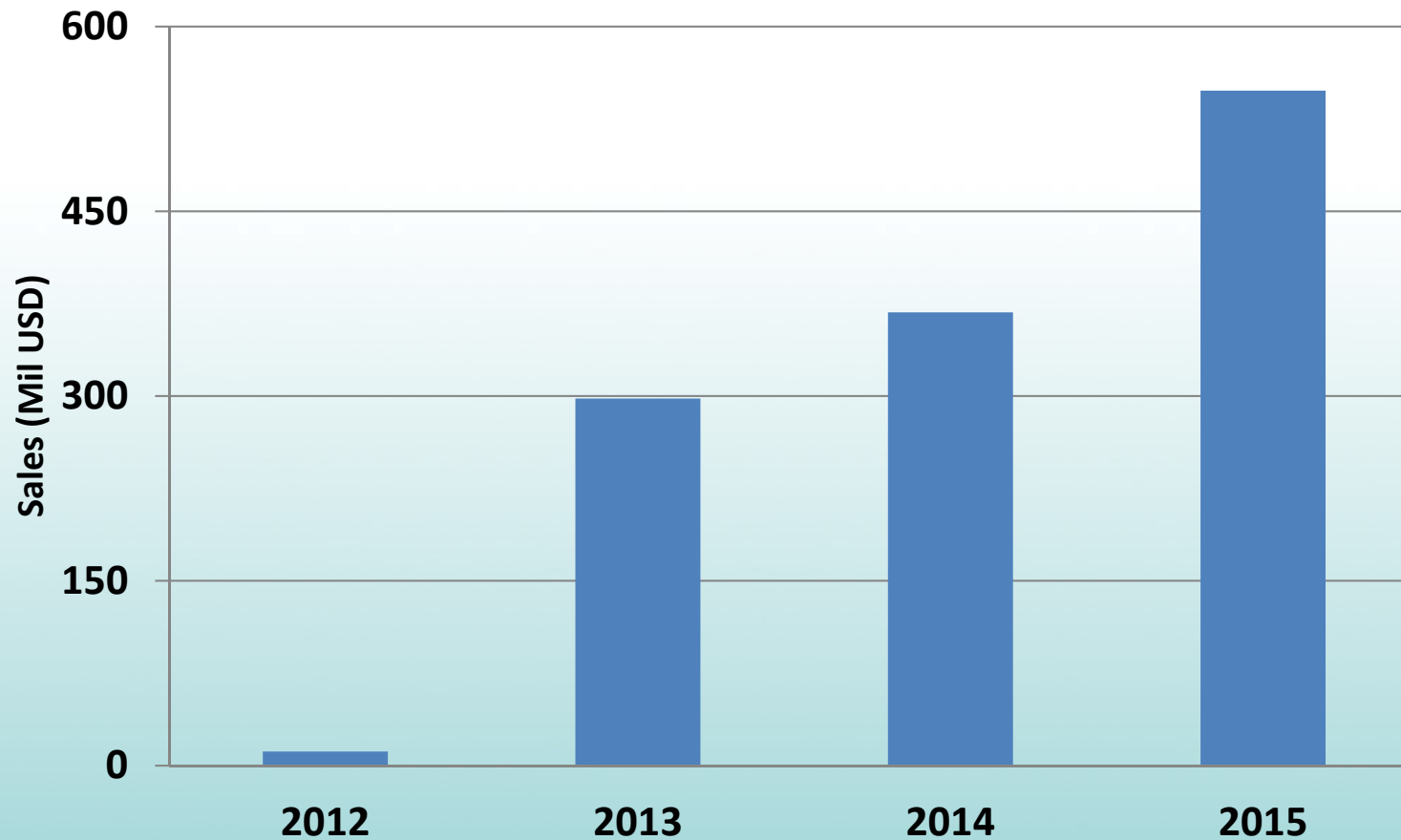
➤ Carfilzomib

- Applicant : Onyx Pharmaceuticals
- Oncology Drug : Kyprolis
- Indication: multiple myeloma.
- Tetrapeptide structure
- Launch at July 2012, US Market sales reach 43 Million Dollars up to date.
- Patent Expiration time : Aug. 2025
- Global 2015 annual sales: 548 Million dollars

Carfilzomib (cont.)



➤ Carfilzomib US Sales



2016 New Products Introduction



➤ Ixazomib citrate

- Brand name: Ninlaro (Takeda)
- Indication: Multiple Myeloma
- FDA approval date: Nov/21/2015
- Sales forecast: More than 700 Million at 2020.
- Patent Expiry: Aug 6, 2027; NCE: Nov20, 2020.

➤ Valsartan/sacubitril

- Brand name: Entresto (Novartis)
- Indication: Heart failure
- FDA approval date: July/07/2015
- Sales forecast: More than 5 Billion at 2019
- Patent Expiry: May 27, 2027; NCE: Jul 07, 2020

➤ Edoxaban Tosylate

- Brand name: Savaysa
- Indication: Anticoagulant
- FDA approval date : Jan/08/2015
- Sales forecast: More than 800 million in 2019
- Patent Expiry: Jun 12, 2023

Worldwide Biotechnology Sales



Unit : USD Billions



Source : World Preview 2015, Outlook To 2020, EvaluatiePharm, 2015

Generics Sales from 2006 to 2020



Unit : USD Billions

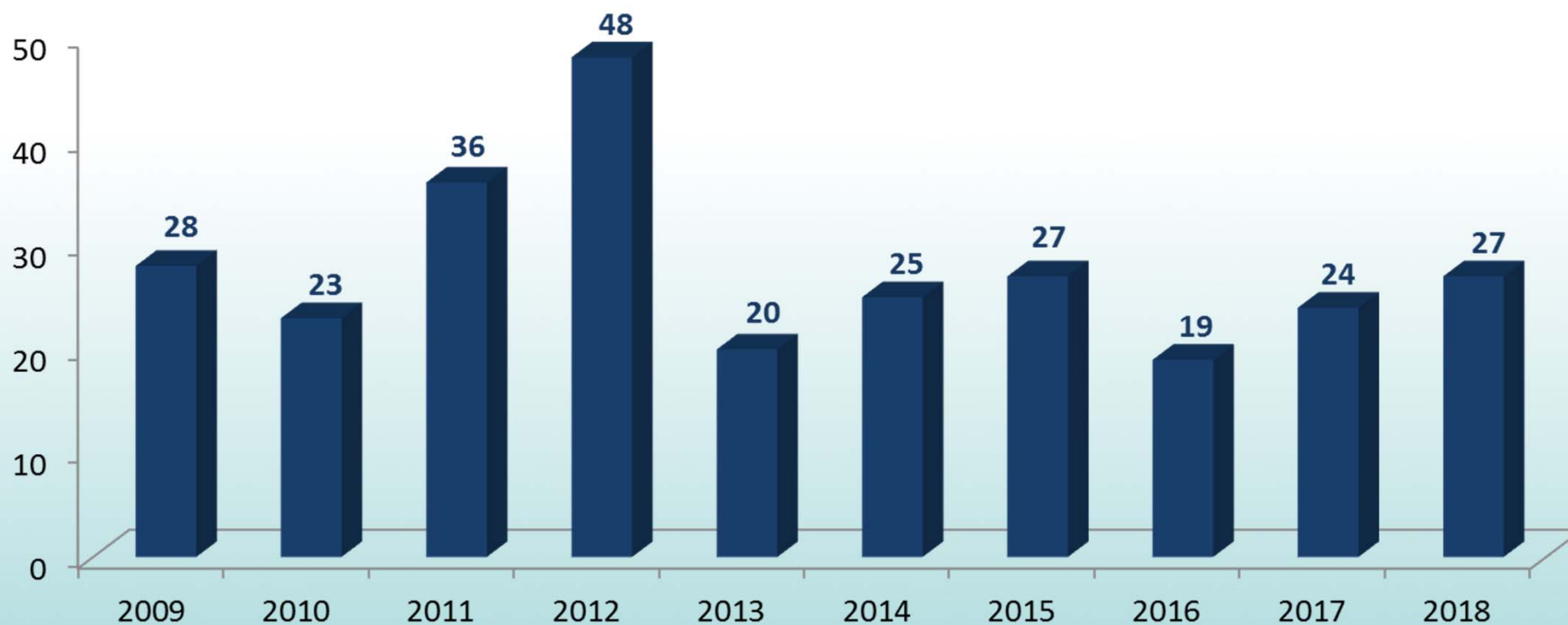


Source : Evaluate © Statista 2015

2009 - 2018 Sales Jeopardized by Patent Expirations

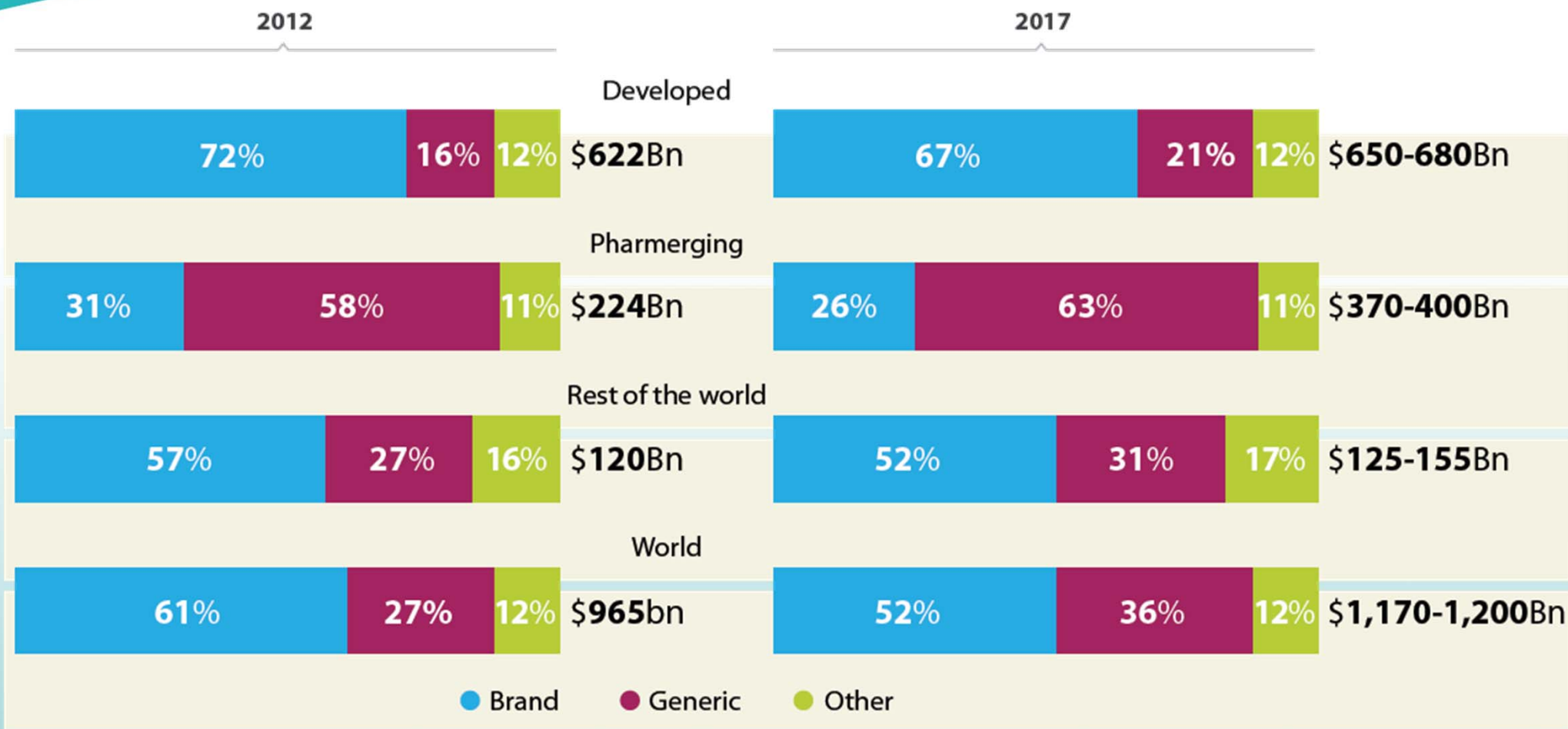


Unit : USD Billions



Source : IMS MIDAS, June 2014

Global Spending, 2012 and 2017



Source : IMS Health Thought Leadership, September 2013

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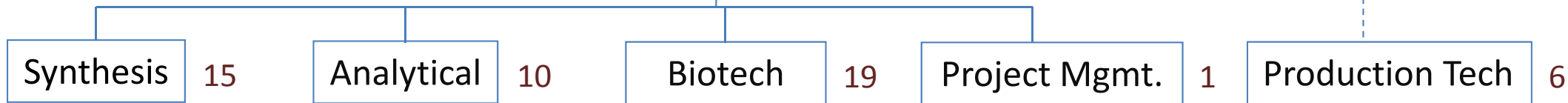
Competitions & Advantages



R&D Functions & Manpower



R&D Division



- Process Research
 - Process Improvement
 - Purification
 - Process Dvpt.
 - Pilot (Scale-up)
- PH.D. 3**
Master 7
Bachelor 5

- Method Dvpt.
 - Analytical Method Validation
 - Specification Set Up
 - Standard Preparation
 - Stability Study
- Ph.D. 1**
Master 6
Bachelor 3

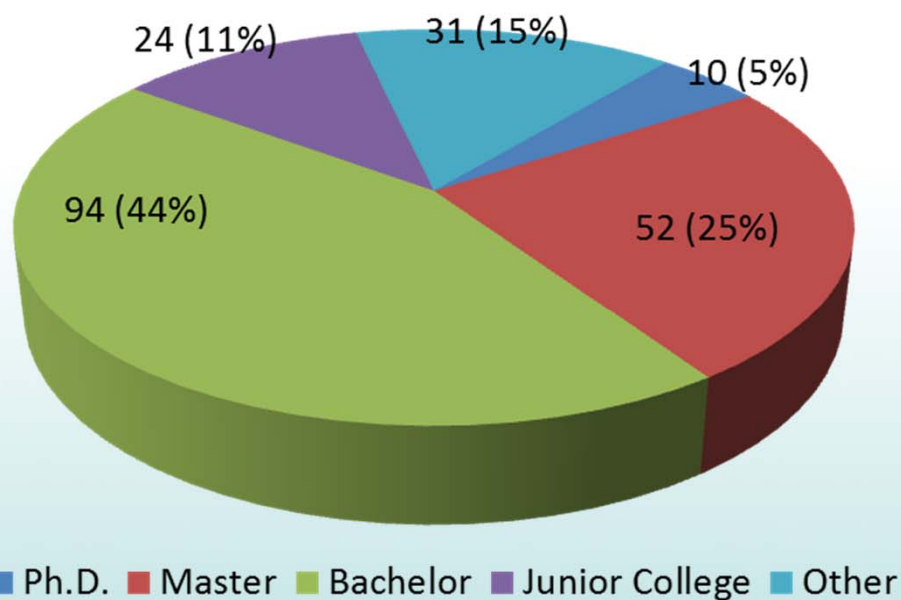
- Strain Improvement
 - Fermentation
 - Process Dvpt.
 - Purification
 - Process Dvpt.
 - Pilot (Scale-up)
 - Peptide & Protein Process Dvpt.
- Ph.D. 5**
Master 10
Bachelor 2
Other 2

- R&D Project Mgmt.
 - Customer Technical Support
 - Patent Mgmt.
- Ph.D. 1**

- Process Optimization
 - Production Tracking
 - Trouble Shooting
 - Production Cost Down
 - Preliminary Sample Preparation
 - CMO
 - CRO
- Ph.D. 2**
Master 2
Bachelor 2

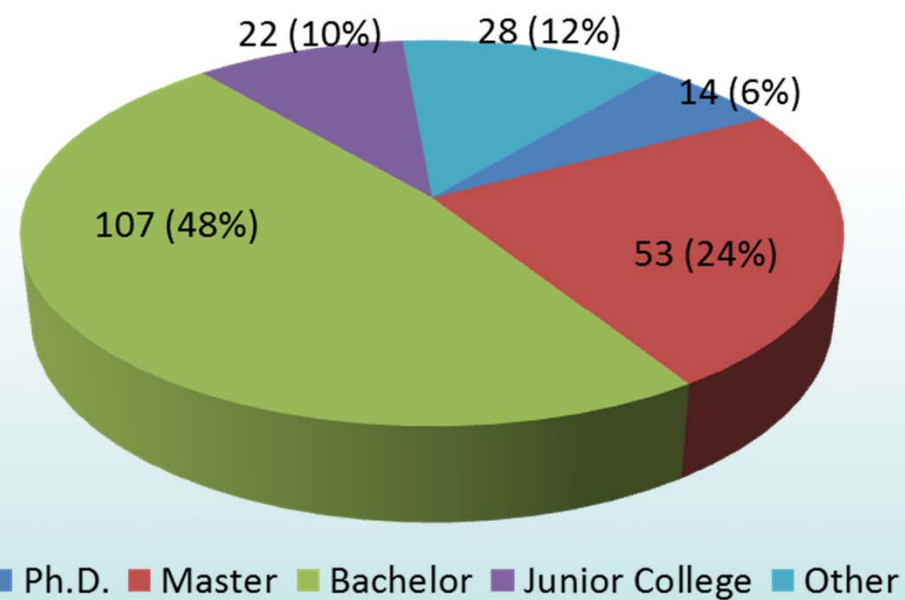
Note : R&D staff headcount at this April end

2015/2016 Manpower Comparison



2015

Note : Total headcount 252 including 41 foreign workers at last April end



2016

Note : Total headcount 268 including 44 foreign workers at this April end

Research Directions



- **Development of asymmetric synthesis, organometallic and halogenation reaction.**
- **To develop products with stable polymorphs.**
- **To combine both microbial fermentation and chemical synthesis to develop products.**
- **To establish gene engineering and biotech high value biological products.**
- **To develop protein and large molecule production technology.**

Short Term Development Plan



- To maintain FDA cGMP validation for all products.
- To maintain USFDA and EU authorities approvals for Biotech products Sirolimus, Everolimus and Tacrolimus.
- To promote Pravastatin and expand market share in USA and Europe markets.
- To enhance new products marketing and increase direct customers in Europe.
- To devote to Tech & Process Improvement, Cost Reduction, Competitiveness and Market Share.
- To strive for more contract manufacturing Contracts (20% of Revenue).
- To seek vendors with qualified raw materials and competitive prices, decrease manufacturing costs and enhance competitiveness.

Long Term Development plan



- To cooperate with pharmaceutical companies and supply APIs for clinical trials.
- To devote to PIV products and generic drugs development.
- To establish key technologies like hydrogenation reaction, chiral resolution reaction, asymmetric synthesis and organometallic reaction.
- To develop series of immunosuppressive and antifungal APIs by fermentation technology; and increase market competition by strengthening the characteristic of APIs product.
- To strive for biotech contract manufacturing as basis of large molecule API production in the long run.
- To develop semi-synthesis products by integrating synthesis and biotech technologies.

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2015 Annual Sales



Unit: NTD Thousands

	Biotech Products	Synthetic Products	Total	%
Domestic	13,386	25,839	39,225	3.4%
Export	851,229	271,757	1,122,986	96.6%
Total	864,615	297,596	1,162,211	100%
%	74.4%	25.6%	100%	—

2014/2015 Annual Sales Comparison



Unit: NTD Thousands

	Y2014	Y2015	Growth	%
Domestic	107,695	39,225	-68,470	-63.6%
Export	839,009	1,122,986	283,977	33.9%
Total	946,704	1,162,211	215,507	22.8%

2014/2015 Income Statement



Unit: Thousand NTD	2014		2015	
	Amount	%	Amount	%
Net Sales	946,704	100%	1,162,211	100%
COGS	649,948	69%	755,738	65%
Net Gross Profit	296,756	31%	406,473	35%
Operating Expenses	273,406	29%	306,958	26%
Operating Income	23,350	2%	99,515	9%
Non-operating Income	14,557	2%	236,591	20%
Income before tax	37,907	4%	336,106	29%
Income Tax Benefit/(Expense)	22,996		27,795	
Net Income	14,911		308,311	
Net Margin	1.57%		26.52%	
EPS(1)	0.19		3.98	

Note: (1) EPS Unit per NTD, shares Outstanding 77.56 Millions

Our Vision



**Expertise the launch of
innovative high-quality API
to pharmaceutical
industries globally**