

中化合成生技股份有限公司

Chunghwa Chemical Synthesis & Biotech Co., Ltd.



C C S B

30<sup>th</sup> May, 2013

Taiwan Discovery Seminar



# 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**

**Plant Expansion Plan**

**Strength & Opportunity**

**Financial Highlights**

**Q & A**

# Agenda



## Business Overview

Major Products & Market Outline

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Q & A

# 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                |
|------|--------------------------|-------------------------|
| 2006 | TFDA                     | PDE                     |
| 2007 | KFDA                     | MCB                     |
| 2008 | NIP<br>TFDA              | TDP<br>RAPA             |
| 2009 | German Authority<br>TFDA | PVTS<br>MCB, PVTS       |
| 2010 | TFDA                     | FK506, MMF              |
| 2011 | USFDA                    | MMF, FK506/SD20, DEXB   |
| 2012 | German Authority<br>TFDA | PVTS<br>FCZ, MATX, RAPA |

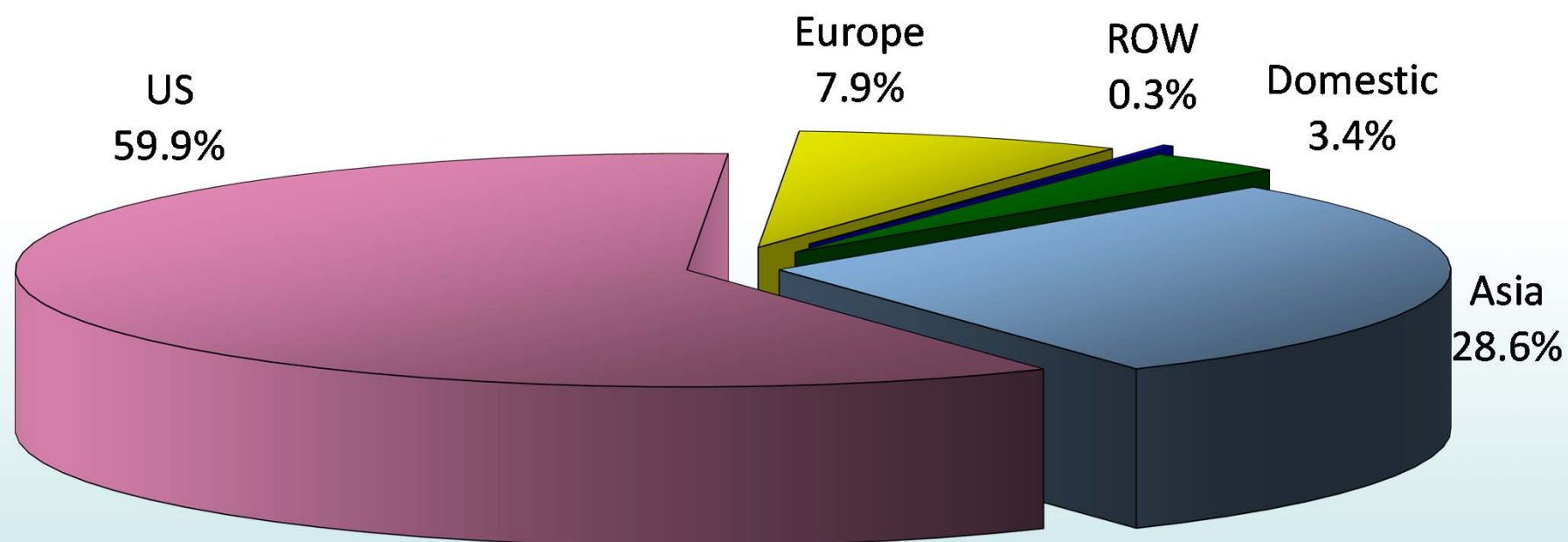
# High Level of Quality (cont.)



## Customers Inspected Products List

| Year | US                                                            | 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, |

# Sales Area in 2012

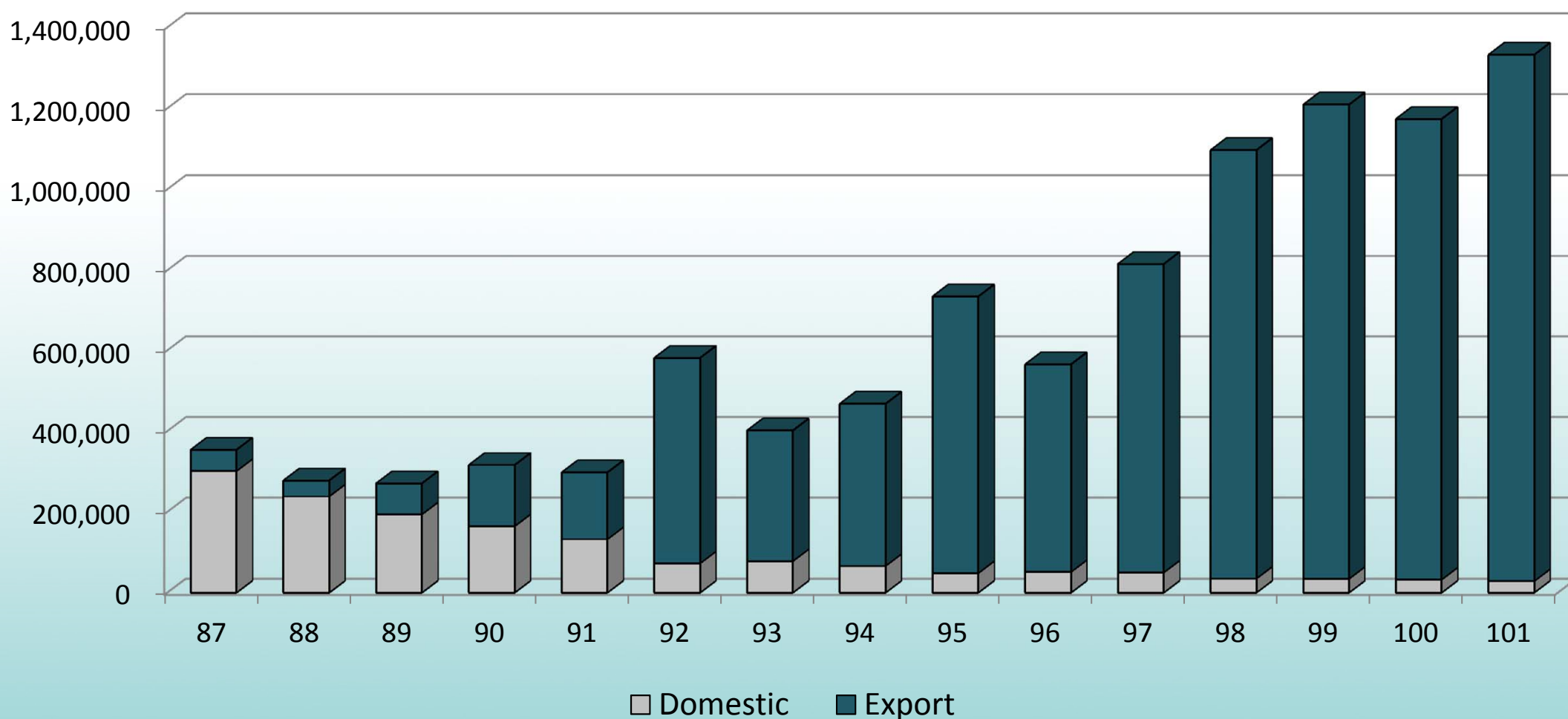


■ Asia ■ US ■ Europe ■ ROW ■ Domestic

# Domestic Sales VS Export Sales



Unit : NTD Thousands



# 2012 Annual Sales



Unit: NTD Thousands

|          | Biotech Products | Synthetic Products | Total     | %     |
|----------|------------------|--------------------|-----------|-------|
| Domestic | 15,257           | 29,530             | 44,787    | 3.4%  |
| Export   | 946,423          | 338,374            | 1,284,797 | 96.6% |
| Total    | 961,680          | 367,904            | 1,329,584 | 100%  |
| %        | 72.3%            | 27.7%              | 100%      |       |

# 2012 YoY



Unit: NTD Thousands

|          | Y2011     | Y2012     | Growth  | %     |
|----------|-----------|-----------|---------|-------|
| Domestic | 43,856    | 44,787    | 931     | 2.1%  |
| Export   | 1,123,970 | 1,284,797 | 160,827 | 14.3% |
| Total    | 1,167,826 | 1,329,584 | 161,758 | 13.8% |

# Agenda



|   |                                            |
|---|--------------------------------------------|
|   | Business Overview                          |
| ✓ | <b>Major Products &amp; Market Outline</b> |
|   | Plant Expansion Plan                       |
|   | Strength & Opportunity                     |
|   | Financial Highlights                       |
|   | Q & A                                      |

# Major Products and Indication



## ➤ Biotech Products

### – Immunosuppressant

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

### – Antihyperlipidaemics

- Pravastatin

### – Anti-cancer

- Everolimus
- Ingenol Mebutate

### – Antifungal

- Caspofungin
- Micafungin

# Major Products and Indication (cont.)



## ➤ Synthetic Products

- **Musculoskeletal Relaxant**
  - Methocarbamol
  - Metaxalone
- **Antihypertension**
  - Trandolapril
- **Antihypertension Intermediate**
  - ZP7
- **Antihistamine**
  - Dexbrompheniramine Maleate
- **Anti-cancer**
  - Carfilzomib
  - Abiraterone
- **Anti-triglycerides**
  - EPA

# New Product Launch



## ➤ Metaxalone

- Musculoskeletal relaxant

## ➤ Micafungin / Caspofungin

- Anti-fungal drug

## ➤ Everolimus

- Anti-cancer drug

## ➤ Carfilzomib

- Anti-cancer drug

## ➤ Ingenol Mabutate

- Anti-cancer drug

## ➤ Abiraterone

- Anti- Prostate cancer drug

# 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 2012 annual sales: 357 Million dollars
- Global 2012 annual sales: 362 Million dollars

# Micafungin



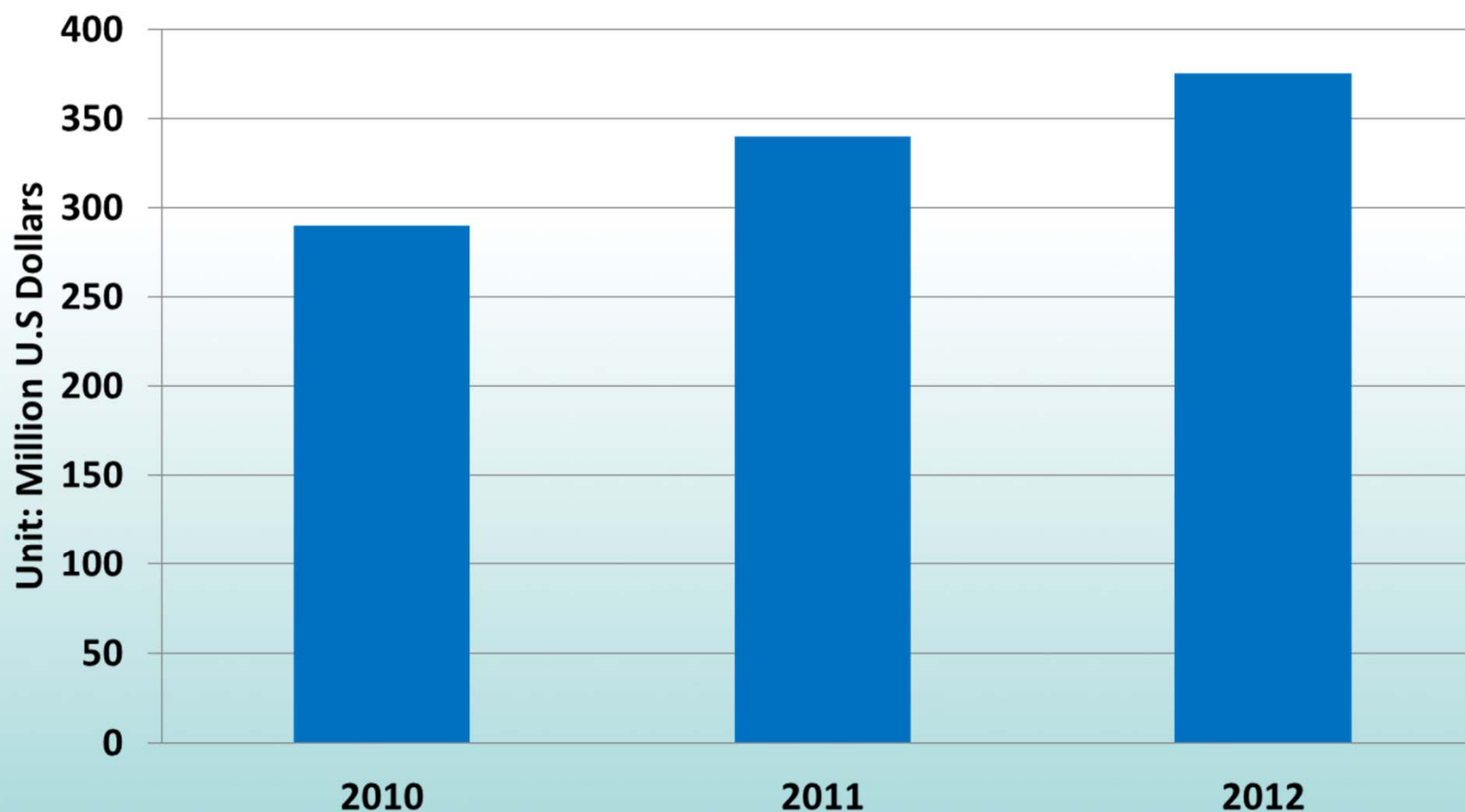
## ➤ Micafungin Sodium

- Applicant: Astellas Pharma
- Antifungal: Mycamine
- Treatment of Patients with Candidemia, Acute Disseminated Candidiasis, *Candida* Peritonitis and Abscesses
- US 2012 annual sales: 113 Million dollars.
- Global 2012 annual sales: 340 Million dollars.

# Micafungin (cont.)



## ➤ Micafungin Worldwide Sales



# Caspofungin



## ➤ Caspofungin Acetate

- Applicant: MERCK
- Antifungal: Cancidas
- Indication: Candidemia and the following Candida infections.  
intra-abdominal abscesses, peritonitis and pleural space infections
- US 2012 annual sales: 46 Million dollars.
- Global 2012 annual sales: 550 Million dollars.

# Everolimus



## ➤ Everolimus

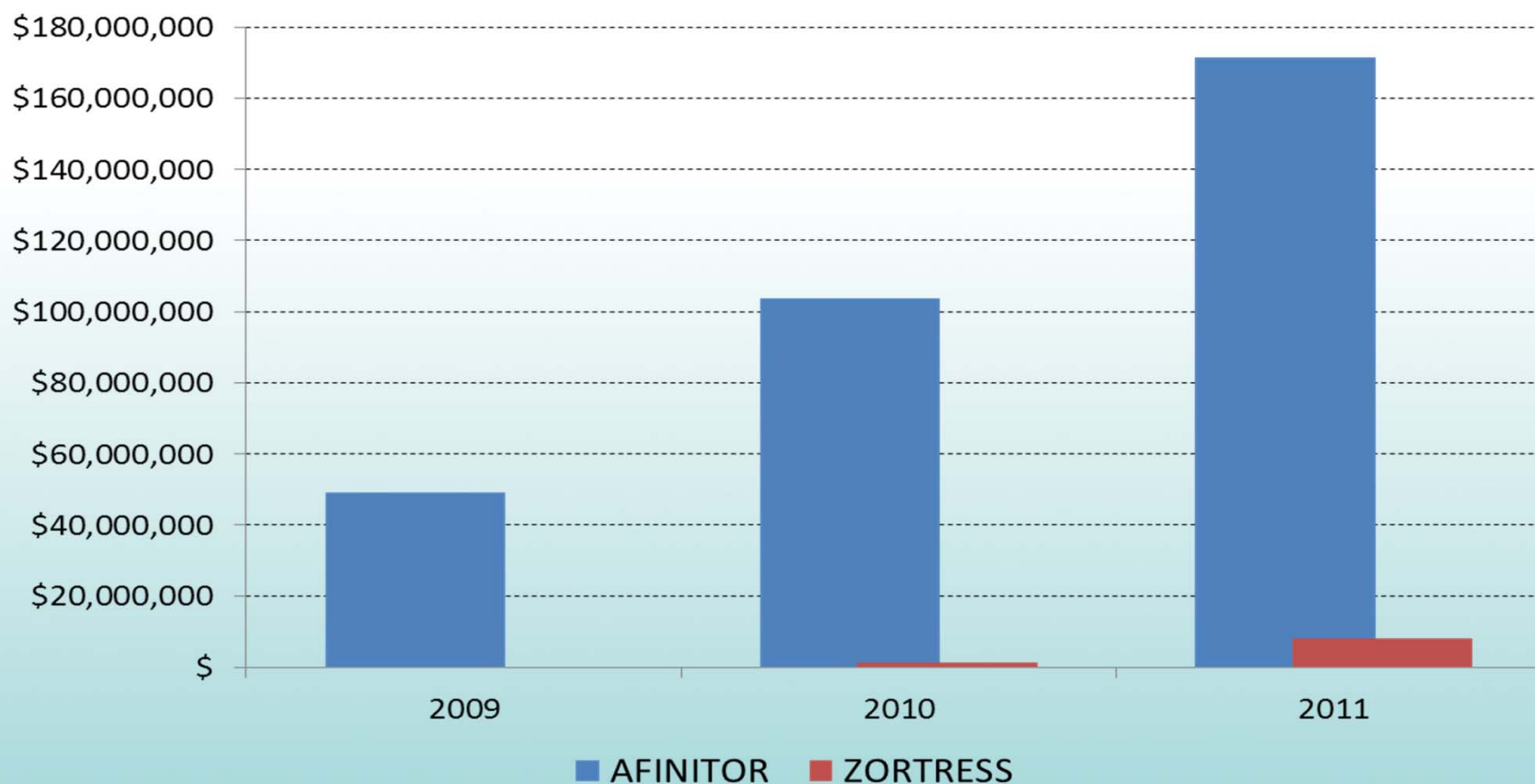
- **Originator: Novartis.**
- **Transplant Drugs: Zortress (US); Certican (Europe & other counties).**
- **To prevent transplant rejection (antirejection medicine) in people who have received a kidney or heart transplant.**
- **Anti-Cancer Drug: Afinitor**
- **Approved for pancreatic cancer and kidney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

# Everolimus (cont.)



## ➤ Everolimus US Market

UNIT: US DOLLARS



# Carfilzomib



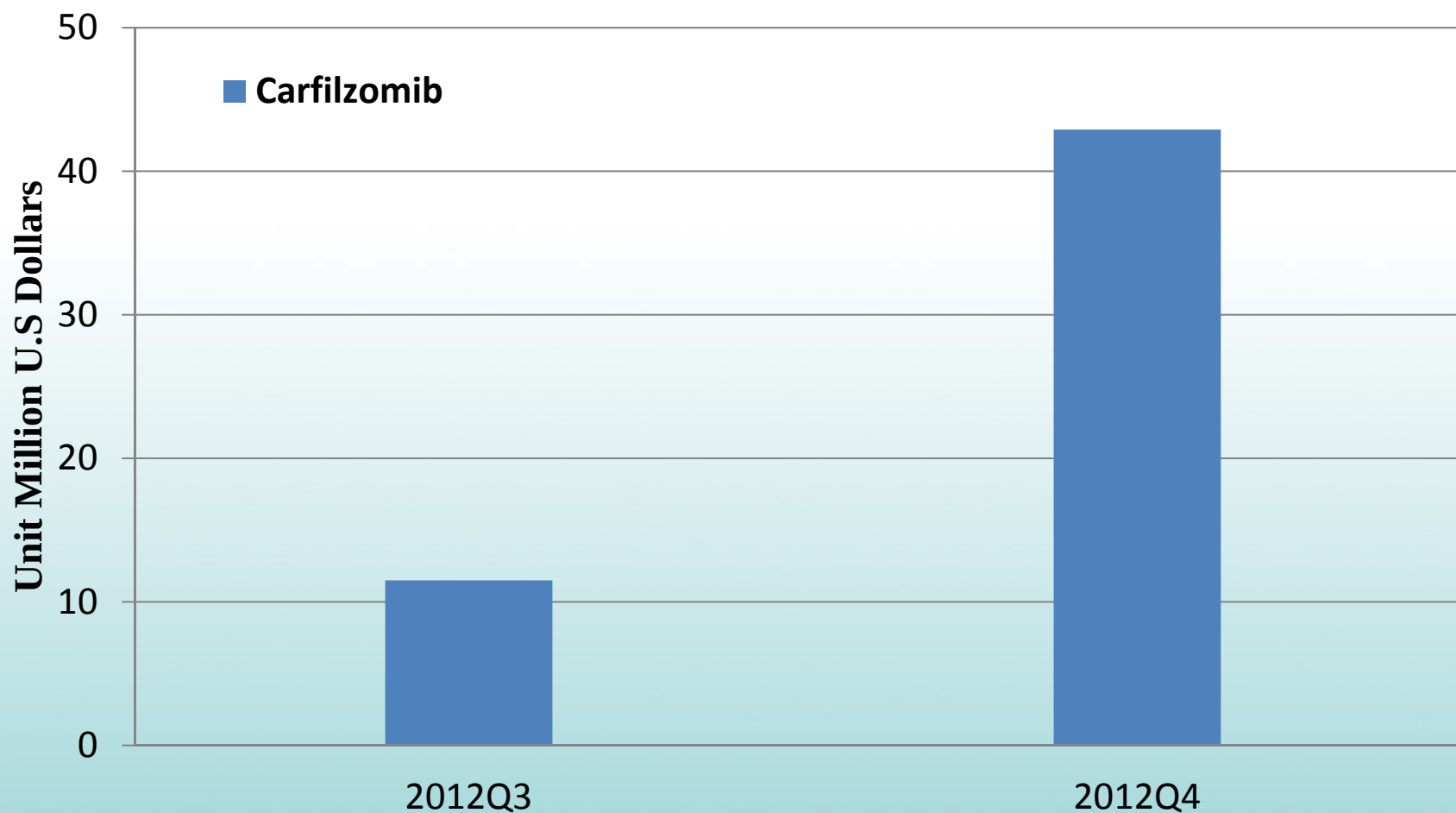
## ➤ Carfilzomib

- Applicant: ONYX PHARMS
- 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

# Carfilzomib (cont.)



## ➤ Carfilzomib US Market sales



# Ingenol Mabutate



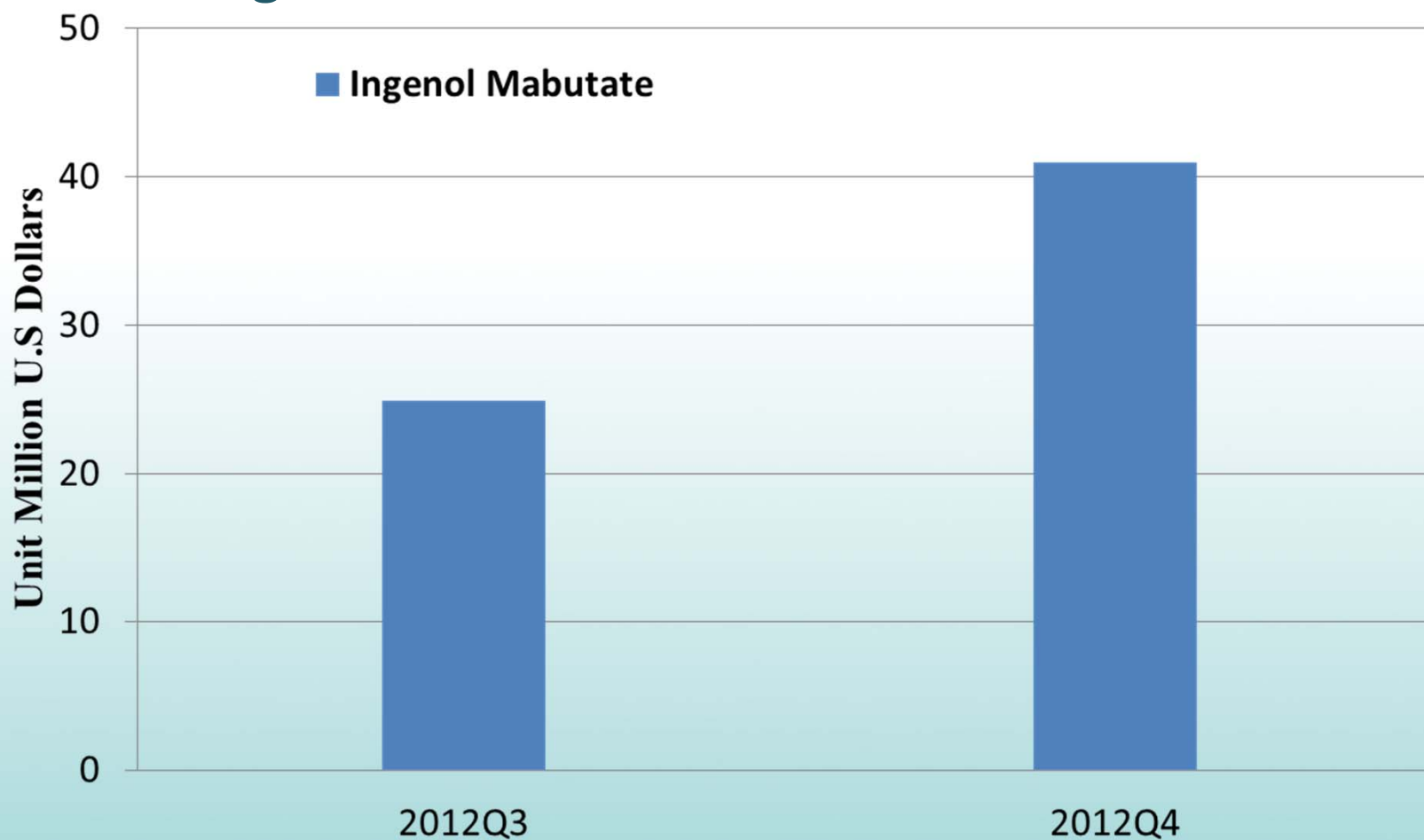
## ➤ Ingenol Mabutate

- 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
- Launch at Jan. 2012. U.S 2012 annual sales: 41 Million dollars.
- Patent Expiration time: Aug. 2018

# Ingenol Mabutate (cont.)



## ➤ Ingenol Mabutate US Market Sales



# Abiraterone



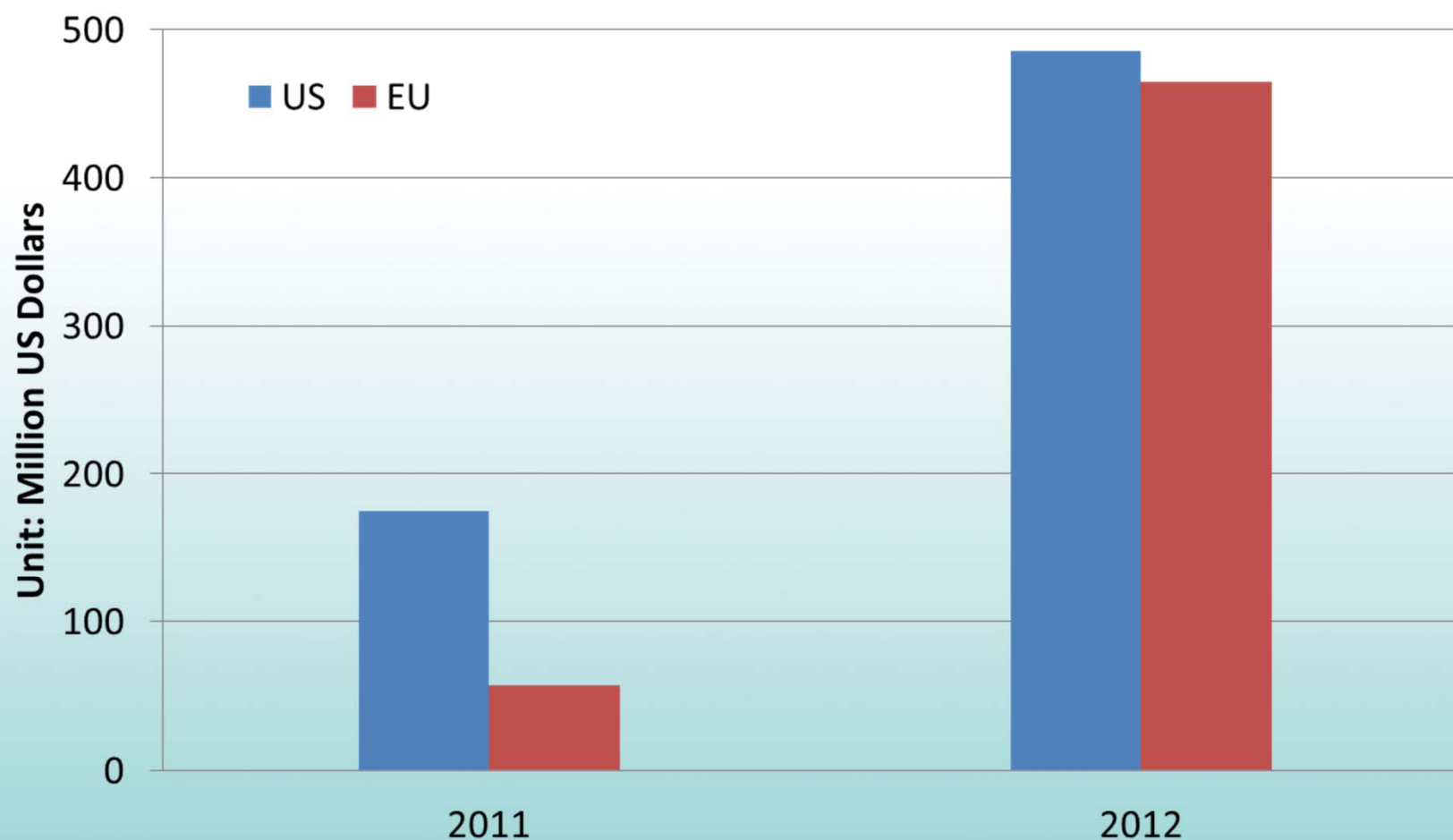
## ➤ Abiraterone Acetate

- Applicant: Johnson & Johnson
- Oncology Drug: ZYTIGA
- Indication: Castration-resistant prostate cancer (formerly hormone-resistant or hormone-refractory prostate cancer)
- Launch at Apr. 2011, U.S Market sales reach 480 Million Dollars up to date.
- Patent Expiration time: Apr. 2016
- Possible next blockbuster of Johnson & Johnson.

# Abiraterone (cont.)



## ➤ Abiraterone Worldwide Market sales



# CCSB Major Products and 2012 Market Size



Unit : Million Dollars

| Products     | US Market sales | Worldwide Market sales |
|--------------|-----------------|------------------------|
| MMF          | 361.6           | 1,236.0                |
| Pravastatin  | 141.6           | 1,171.0                |
| Rapamycin    | 200.2           | 309.6                  |
| Tacrolimus   | 954.8           | 2,606.0                |
| Micafungin   | 106.6           | 299.7                  |
| Caspofungin  | 62.9            | 554.3                  |
| Metaxalone   | 380.0           | 383.9                  |
| Everolimus   | 147.1           | 492.4                  |
| Temsirolimus | 71.1            | 140.0                  |

# Agenda



|   |                             |
|---|-----------------------------|
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|   | Products & Market Outline   |
| ✓ | <b>Plant Expansion Plan</b> |
|   | Strength & Opportunity      |
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|   | Q & A                       |

# Plant Expansion Plan



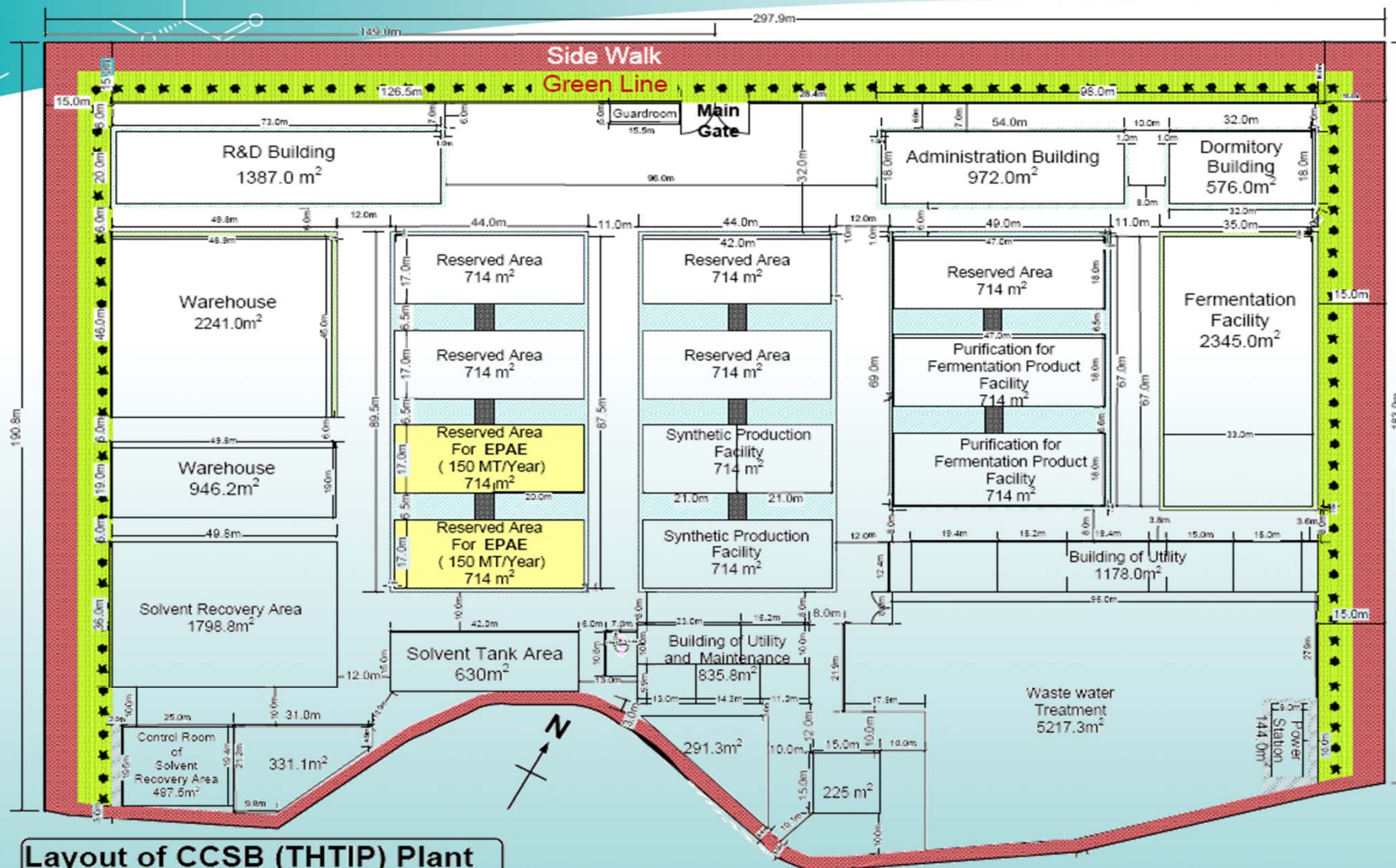
- With increasing demand and items, the current production capacity will be fully occupied.
- It is foreseen both existing and new products will grow sharply down to 2015, there's an urgent need to expand current capacity.
  - Land bought in 2012 April in Taoyuan High-Tech Industrial Park
  - Area: 16,060 Ping
  - Investment: NTD682,564,000
  - Operation starts: 2016Q1
  - Standard: Comply with cGMP of regulated countries.

# New Plant Construction Estimated Agenda



| Timeline<br>Tasks |                           | 2012 |    |    |    | 2013 |    |    |    | 2014 |    |    |    | 2015 |    |    |    | 2016 |    |    |    |
|-------------------|---------------------------|------|----|----|----|------|----|----|----|------|----|----|----|------|----|----|----|------|----|----|----|
|                   |                           | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 |
| 1                 | Concept Design (Internal) |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 2                 | Concept Design (External) |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 3                 | Detailed Design           |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 4                 | Contract Out              |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 5                 | Licence Application       |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 6                 | Groundbreaking            |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 7                 | Construction Phase I      |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 8                 | Facilities Trial          |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 9                 | Trial Run                 |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 10                | Process Validation        |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 11                | Customer Approval         |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 12                | FDA Inspection            |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
| 13                | Commercialization         |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |

# New Plant Layout



## Layout of CCSB (THTIP) Plant

Location at Taoyuan High-Tech Industrial Park(THTIP)  
Taiwan

Update : 2013.03.06

# New Plant Exterior Preview



# Phase I Construction Exterior Preview



# Dormitory, Fermentation and Synthesis Plant Preview



# Agenda



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**Strength & Opportunity**

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# Advantage



- **US FDA and EU PIC/S GMP Regulatory Inspection Qualified.**
- **DMFs Filed to Aim for Export.**
- **API Manufacturing Combining Fermentation and Synthesis Process .**
- **Small Scale API Synthesis to Support Customer R&D.**
- **Speed up new product developing by establishing cooperation relationship with research labs in different countries.**

# Short Term Development Plan



- To promote Pravastatin and expand market share in USA, Europe and Japan 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 (30% of Revenue)
- To seek vendors with qualified raw materials and competitive prices, decrease manufacturing costs and improve competitiveness.
- To establish strategic alliance with pharmaceutical companies to develop other new qualified products to explore the world-wide market.

# Medium Term Development Plan



- To cooperate with pharmaceutical companies and supply APIs for clinical trials
- To devote to generic drugs development (equally on PIV & PIII products)
- To develop specialty chemical and intermediate
- To strive for biotech contract manufacturing as basis of large molecule API production in the long run
- To leverage the fusion of synthesis and fermentation to develop niche product

# Long Term Development plan



- Cooperation with Academic and Authority to develop Small Molecular New Entity.
- Upgrade Current Fermentation Process to Cell Culture Technology.
- Cooperation with Academic and Authority to develop New Biological Product.

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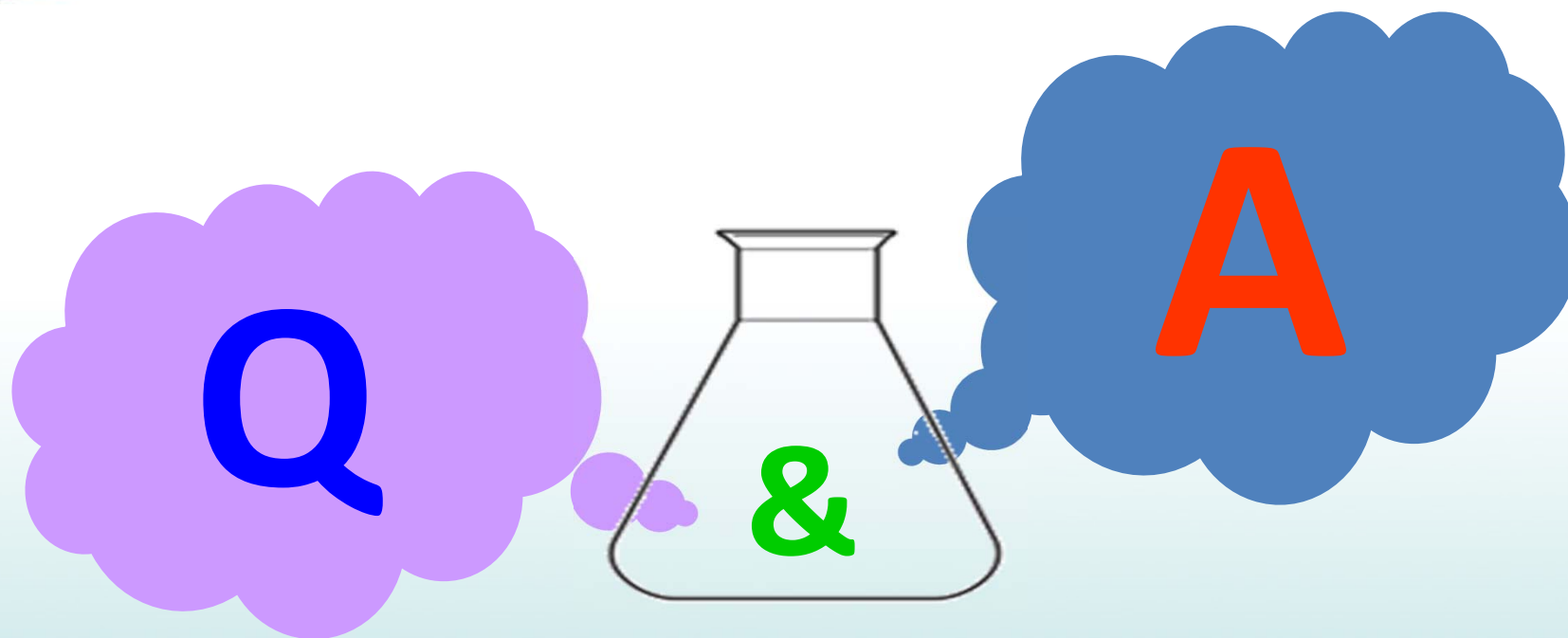
# 2012 Income Statement



Unit: Thousand NTD

|                                     | Amount           | %           |
|-------------------------------------|------------------|-------------|
| <b>Net Sales</b>                    | <b>1,329,584</b> | <b>100%</b> |
| COGS                                | 809,288          | 61%         |
| <b>Net Gross Profit</b>             | <b>496,527</b>   | <b>37%</b>  |
| Operating Expenses                  | 294,385          | 22%         |
| Operating Income                    | 202,142          | 15%         |
| <b>Non-operating Income</b>         | <b>20,049</b>    | <b>2%</b>   |
| Non-operating Expenses              | 15,733           | 1%          |
| Income before tax                   | 206,458          | 16%         |
| <b>Income Tax Benefit/(Expense)</b> | <b>30,894</b>    |             |
| Net Income                          | 175,564          |             |
| <b>Net Margin</b>                   | <b>13.2%</b>     |             |
| <b>EPS(1)</b>                       | <b>2.26</b>      |             |

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



**Thank You!**