

The logo features the letters 'TTV' in a bold, red, italicized font, followed by 'BIOPHARM' in a white, italicized font with a registered trademark symbol. The entire logo is set against a black diamond-shaped background.

**TTV** BIOPHARM®

台灣東洋藥品

**WELCOME TO JOIN US**

May, 2019

# Safe Harbor Statement

## This presentation contains certain forward-looking statements.

These forward-looking statements may be identified by words such as 'believes', 'expects', 'anticipates', 'projects', 'intends', 'should', 'seeks', 'estimates', 'future' or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

1. pricing and product initiatives of competitors;
2. legislative and regulatory developments and economic conditions;
3. delay or inability in obtaining regulatory approvals or bringing products to market;
4. fluctuations in currency exchange rates and general financial market conditions;
5. uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;

6. increased government pricing pressures;
7. interruptions in production
8. loss of or inability to obtain adequate protection for intellectual property rights;
9. litigation;
10. loss of key executives or other employees; and
11. adverse publicity and news coverage.

TTY Biopharm cautions that this foregoing list of factors is not exhaustive. There may also be other risks that management is unable to predict at this time that may cause actual results to differ materially from those in forward-looking statements.

**You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. TTY Biopharm undertakes no obligation to update publicly or revise any forward-looking statements.** Any statements regarding earnings growth is not a profit forecast and should not be interpreted to mean that TTY Biopharm's earnings or earnings per share for this year or any subsequent period will necessarily match or exceed published earnings or earnings per share forecasts of TTY Biopharm Company Limited.

# Our Mission

We have been striving to extend liposomal & microsphere depot platform technologies for treatment of various diseases.

**Our Target is to improve health and quality of life through innovative, cost-effective therapeutics and specialty drugs.**

Our focus is on the **“Unmet Medical Needs”** in challenging diseases throughout the world, such as Cancer, CNS, Autoimmune, Diabetes Mellitus & Infectious Diseases.

# Agenda

## Company Overview

Product Strategy

Product Pipeline

Manufacture Facilities

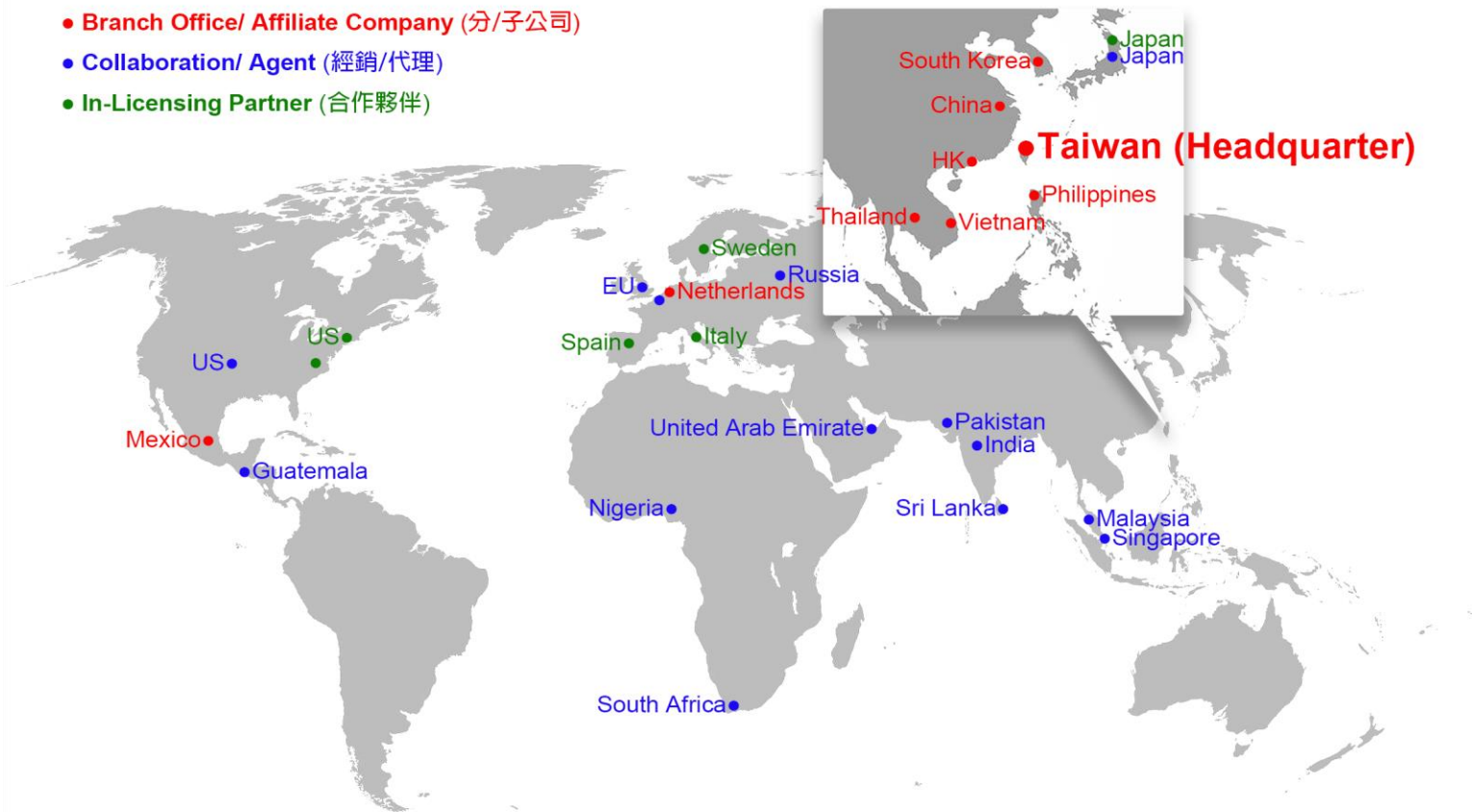
Successful Product Categories

In Progress Status

Biotech Success

# Company Overview

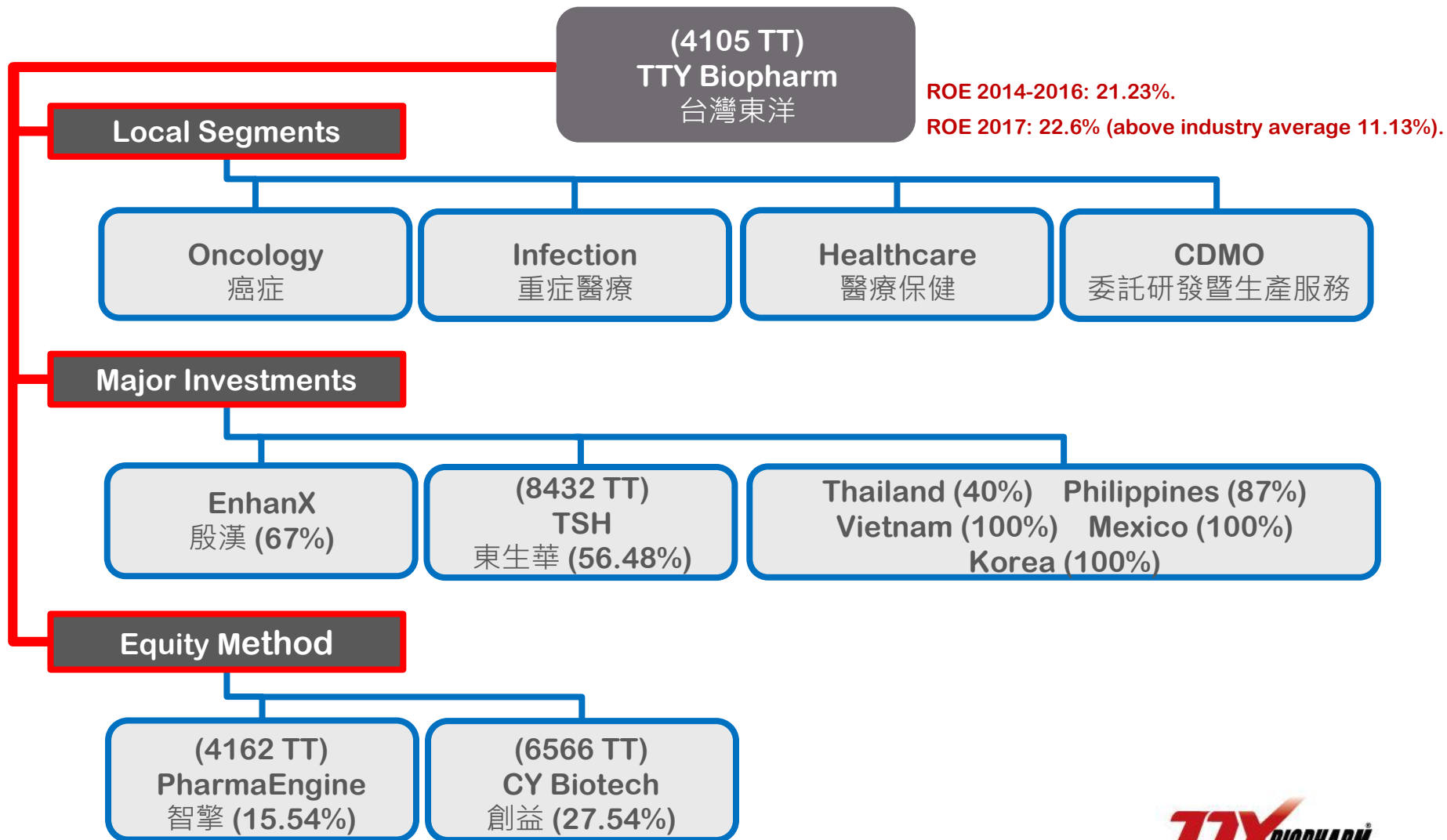
- Branch Office/ Affiliate Company (分/子公司)
- Collaboration/ Agent (經銷/代理)
- In-Licensing Partner (合作夥伴)



- Founded in 1960, restructured in 1996
- Traded in the Taiwan TPEX (2001, Code: 4105);
- Shares outstanding: 248.65 Million Shares (December, 2018)

- TTY Biopharm consolidated sales as of  
2018- NTD 4.06B (USD 132M) Unaudited  
2017- NTD 4.08B (USD 134M)

Headquarter: Taipei, Taiwan  
Number of employees: 530



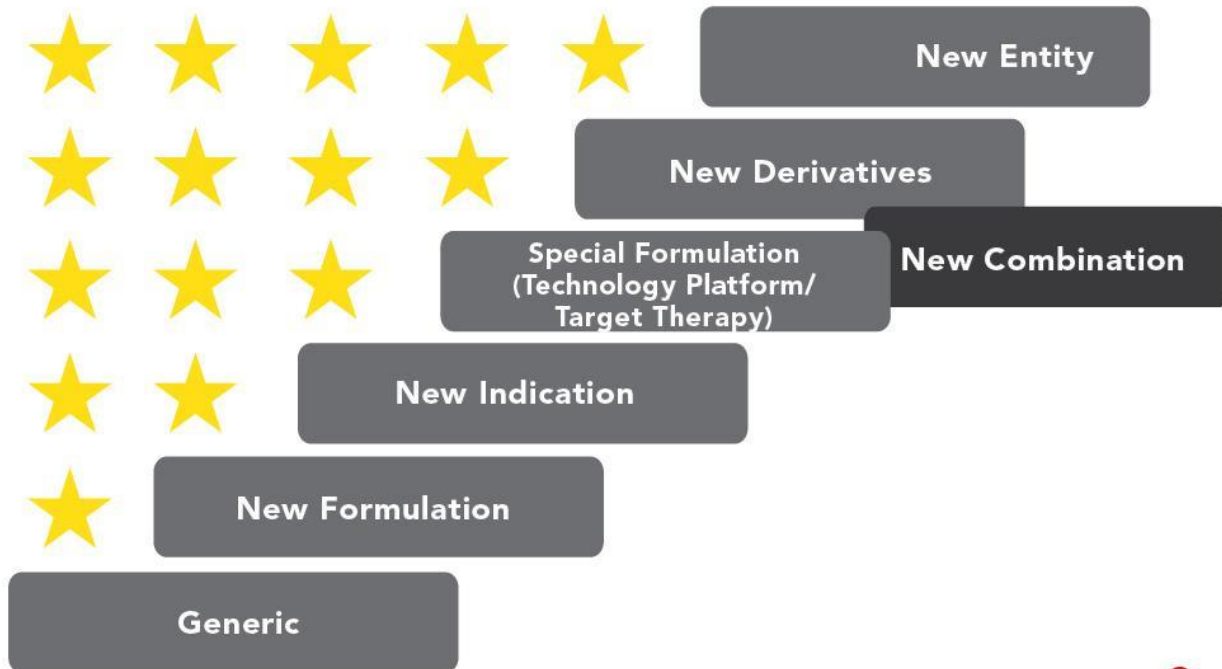
# TTY 核心能力



# Product Strategy

## Trends for Pharmaceutical Industry

Market Scope  
(Risk)



Entry Barrier  
(Profit)





# Agenda

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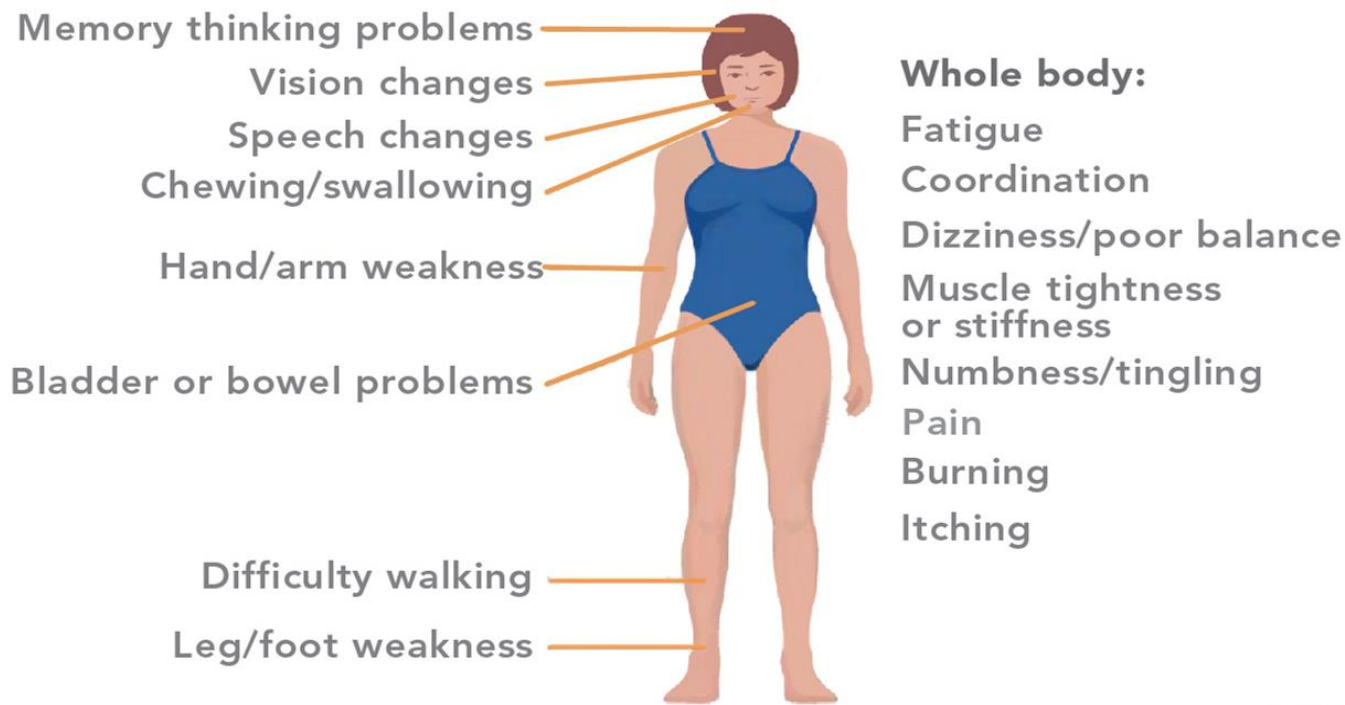
產品組合	World Market USD/M	核心技術	產品優勢
Caelyx/Doxil <b>Pegylipo</b>	600	Pegylated Liposome Technology	Worldwide Manufacturing Patent
Lipo-AB	440	Liposome Technology	Worldwide Manufacturing Patent
Octreotide	1,500	Microsphere Formulation	PLGA, Star Polymers Synthesized by TTY.
Colimycin	150	Formulation	First Choice Irreplaceable Options, TWNIH
ENX-201	1,700	Liposome Technology	Penetrating Blood-Brain-Barrier (BBB) capability
Leuprolide Acetate Injection	1,240	Lupron Depot Microsphere Formulation	Worldwide Manufacturing Patent
Risperidone Injection	960	Microsphere Formulation	Worldwide Manufacturing Patent
LGIA10	910	Microsphere Formulation	Worldwide Manufacturing Patent Microsphere Depot Platform

# Introduction of MS

## MS: a chronic, autoimmune & neurodegenerative disorder

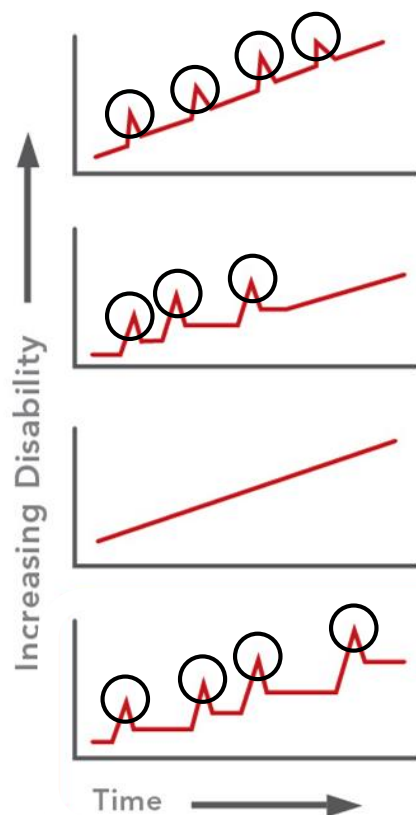
### Body's own defensive system attacks myelin

- Inflammatory damage in the brain and spinal cord
- Loss of myelin and axons (scars at multiple sites)
- Neurologic disability



# Introduction of MS

## Four Classifications of MS



**PRMS** Progressive Relapsing MS  
Steady decline since onset with super-imposed attacks.

**SPMS** Secondary Progressive MS  
Initial RRMS that suddenly begins to decline without periods of remission and relapses.

**PPMS** Primary Progressive MS  
Gradual progression of the disease from its onset with no relapses or remissions

**RRMS** Relapsing/Remitting MS **85%~90% patients**  
Unpredictable attacks which may or may not leave permanent deficits followed by periods of remission

**Either one of the four classifications occurs in acute is the target patient pool of ENX-201.**  
不管屬於哪一個發病類型，只要是急性復發，就是ENX-201的target病患。

# Introduction of MS

**World distribution of multiple sclerosis: greater prevalence in higher northern and southern latitudes**

## GLOBAL DISTRIBUTION OF MS

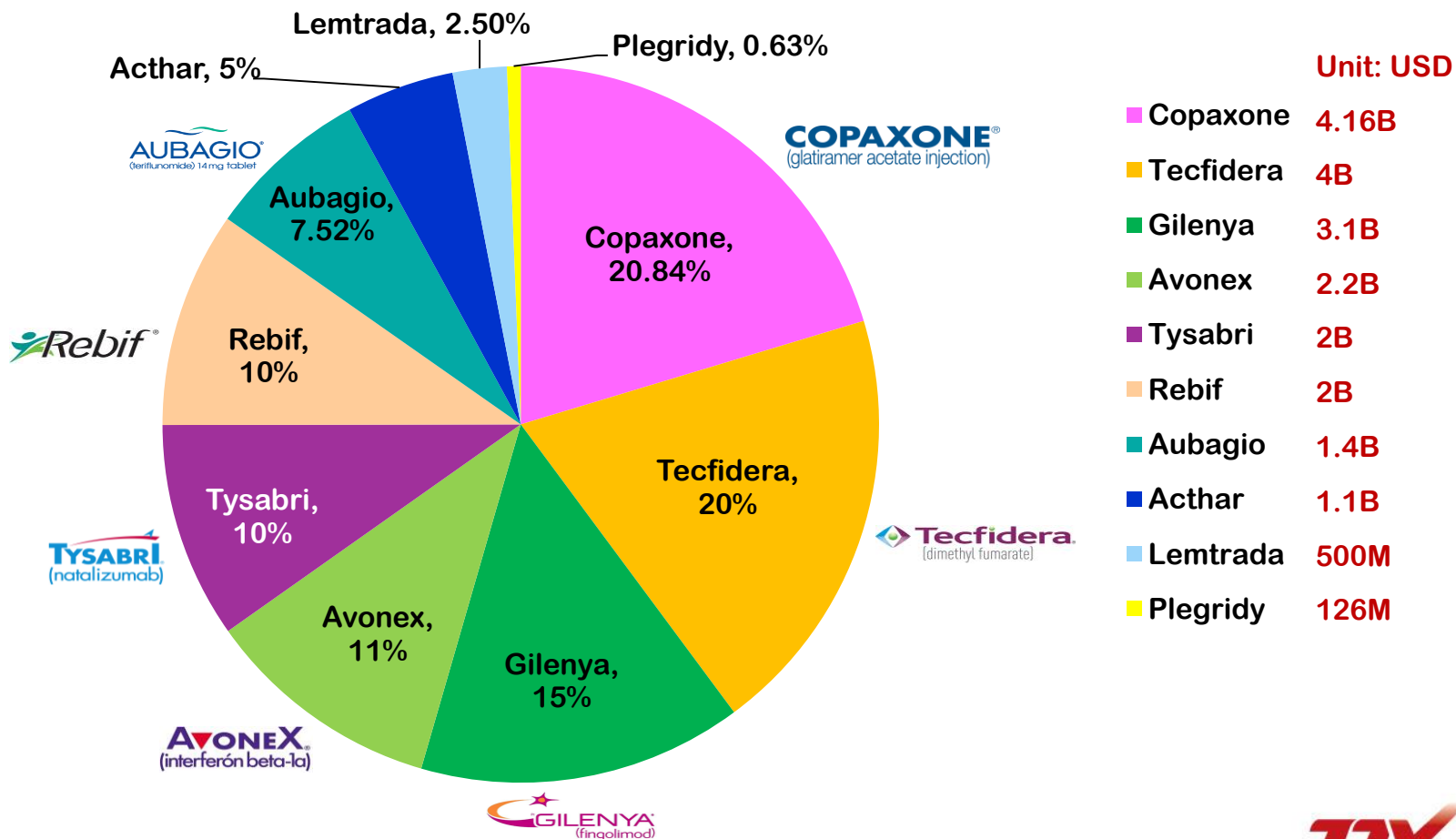


女 : 男 = 2 ~ 3 : 1

Around  
2.5 millions

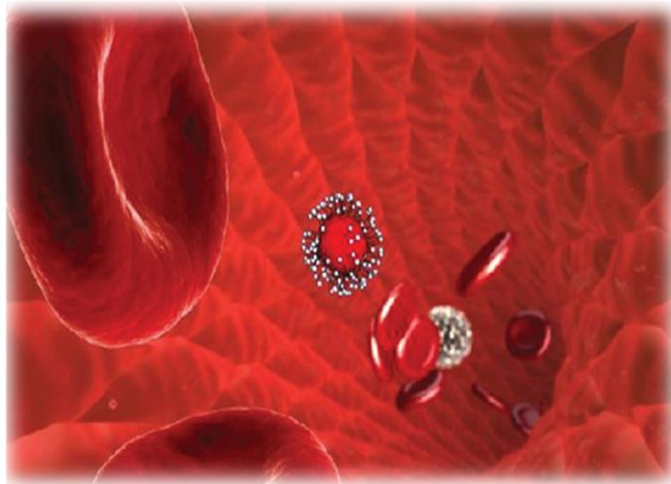
# Introduction of MS

Major existing choices for MS treatments (2016 Sales & Market Share in Value)

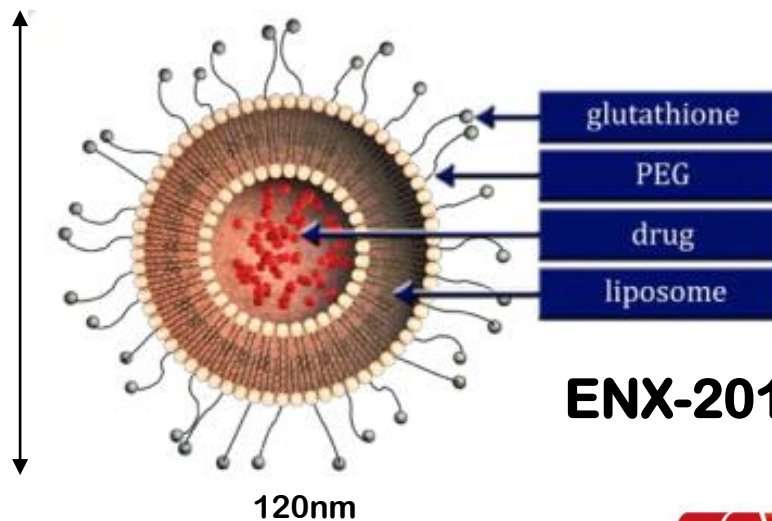


<https://www.fool.com/investing/2016/07/26/an-investing-overview-of-the-multiple-sclerosis-ma.aspx>

# Introduction of the Product

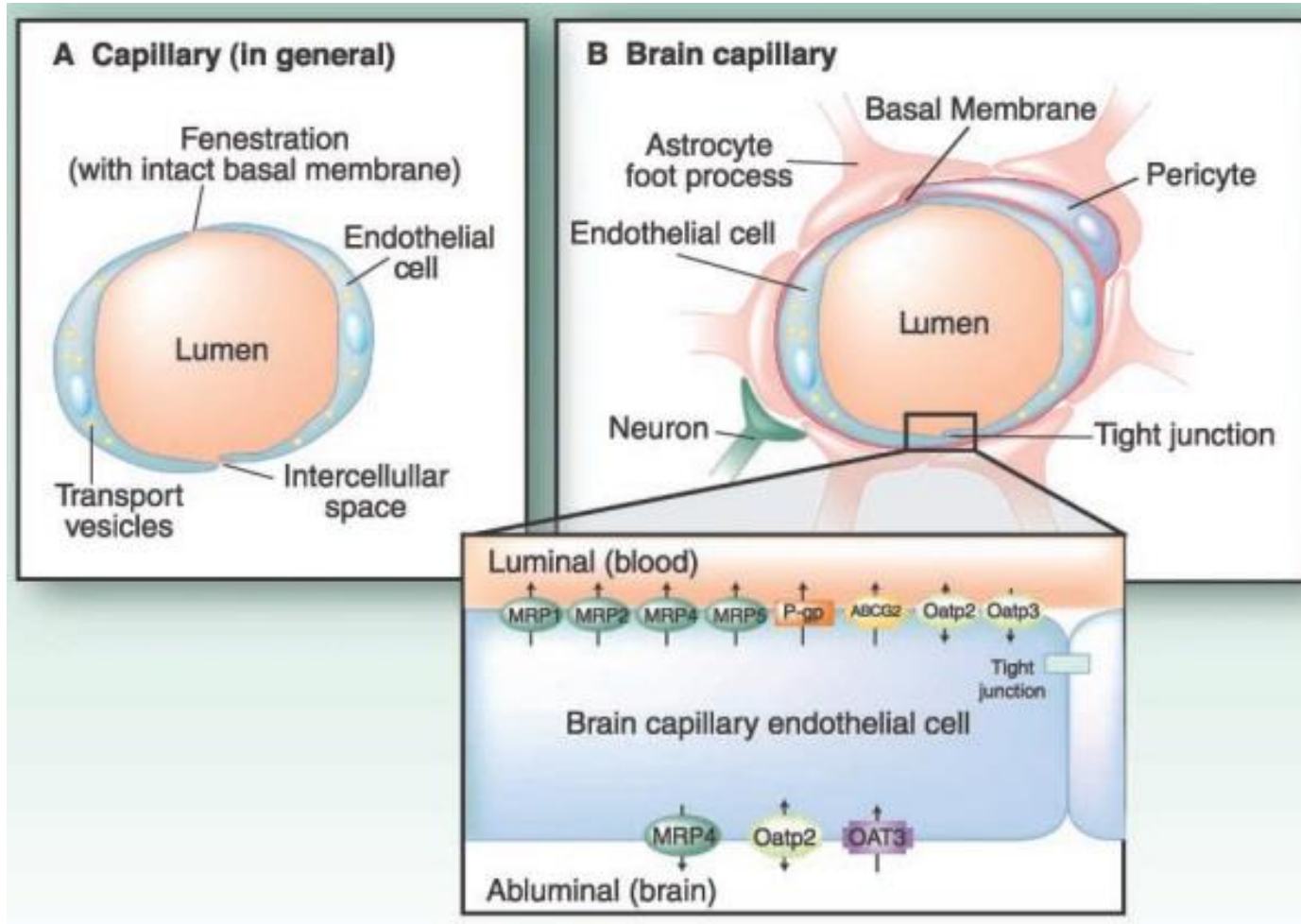


Targeting Liposomal Methylprednisolone Injection (glutathione PEGylated liposomal methylprednisolone) is being developed for patients suffering from acute and chronic neuro-inflammatory diseases, with an initial focus on patients with acute MS relapses.



**ENX-201**

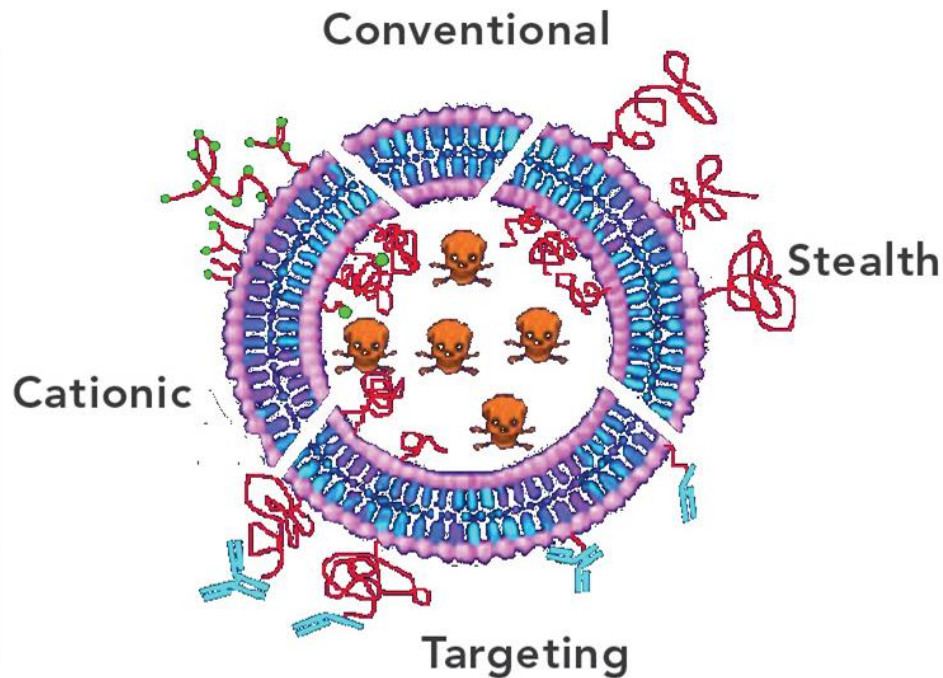
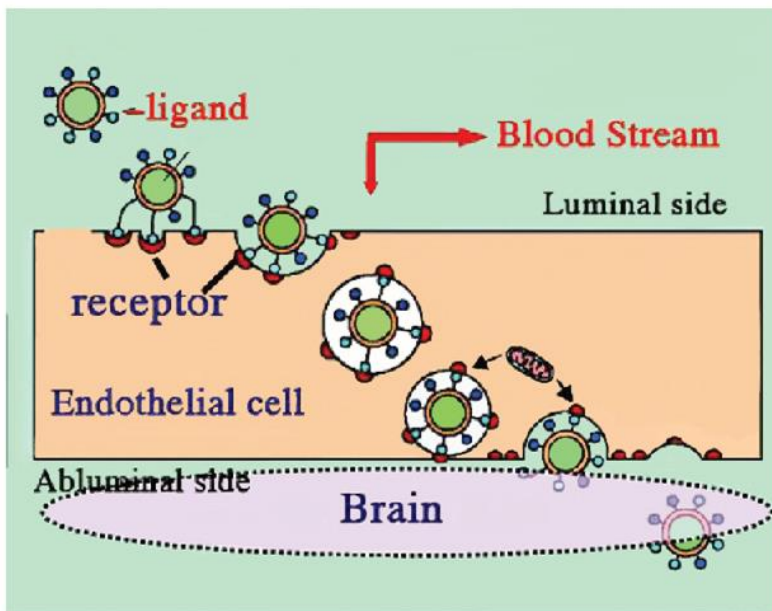
# Introduction of BBB





# ENX-201 Introduction

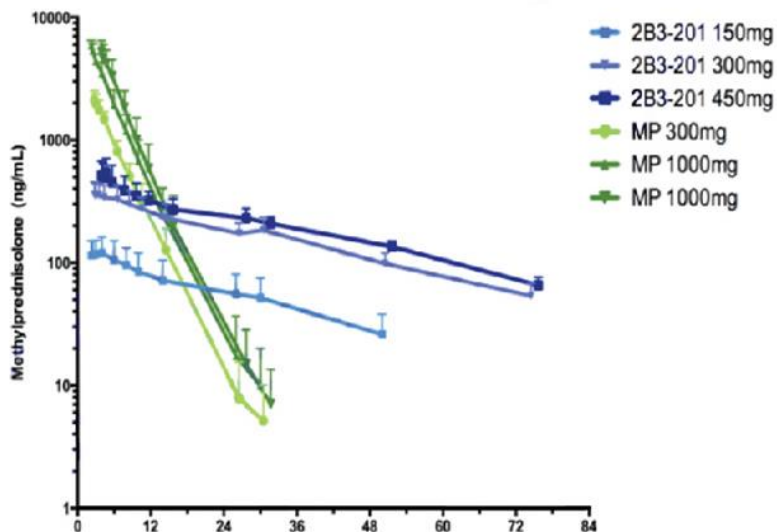
## Effective drug delivery to across the blood-brain barrier (BBB)



# Phase I Study (Solution)

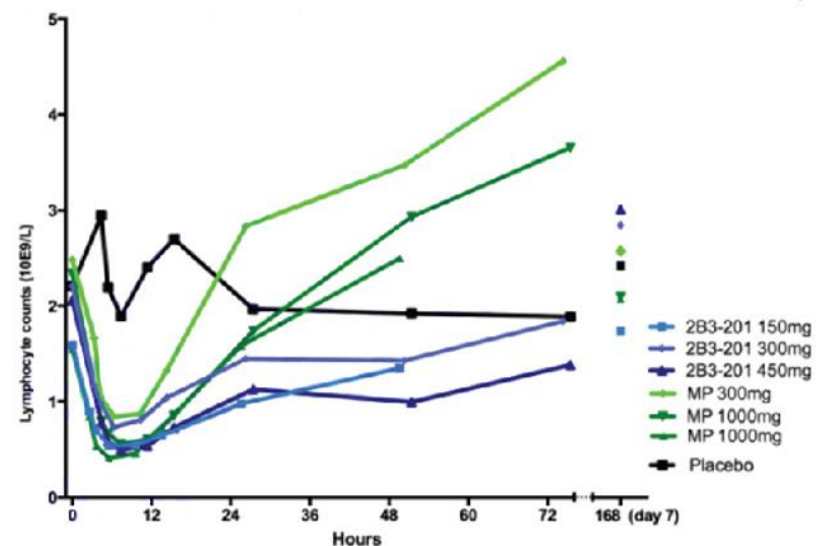
## Phase I dose-escalation results Pharmacokinetics

- Long circulation half-life of ENX-201 (23~28 hrs) vs. MP (2.5 hrs)
- Reduced high peak exposure



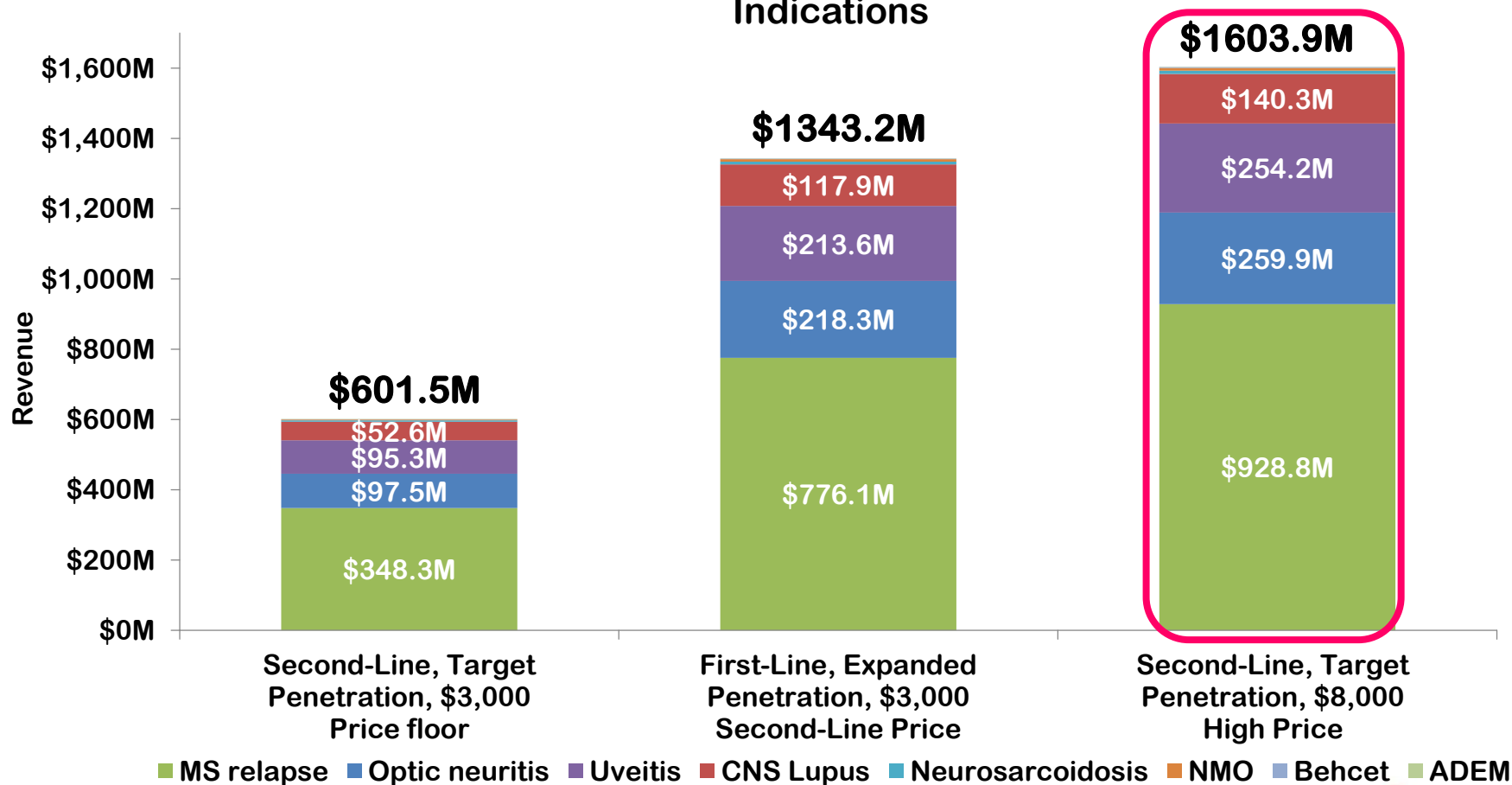
## Phase I dose-escalation results Effect on lymphocytes

- Rapid and sustained immunosuppressive effect
- Lymphocyte count crossed baseline within 7 days in all groups



# Potential Market Size

## ENX-201 US Peak Year Revenue – MS & Other Inflammatory Indications



# Development Strategies

## ▪ ENX-201's strengths

- *ENX-201 is a pegylated liposome which glutathione is attached on its lipid, while methylprednisolone as the main substance is encapsulated inside.*
- *Compared with the standard of care, i.e., a free methylprednisolone, ENX-201 is an **one-shot** intravenous injection which brings home-care convenience and better tolerance to patients suffering acute multiple sclerosis relapses.*



# Multiple Indications to Go (Pipeline)

	Indications to Develop	Market Potential Size	Competitors
1	Multiple Sclerosis (多發性硬化症)	>21.5B	Teva (2014) Biogen EMD Serono Novartis
2	Uveitis (葡萄膜炎) (眼睛發炎)	>0.531B	Humira (2016)
3	Neuropathic Pain (神經性疼痛)	>5.7B	Pfizer (2011)
4	Osteoarthritis (骨關節炎)	>5.335B	Anika (2014)
5	ALS (漸凍人-肌萎縮性脊髓側索硬化症)	>25M (a negative CAGR of 16.10%)	Biogen Idec Inc. Avanir Pharmaceuticals Inc. Isis Pharmaceuticals Inc. Sanofi Bristol-Meyers Squibb Co.
6	Mucopolysaccharidoses (MPS, 黏多醣症)	>300M	Vimizim
7	Metachromatic leukodystrophy (MLD, 異染性腦白質失養症)	1B	Shire Plc Nuo Therapeutics GlaxoSmithKline Plc Zymenex A/S RegenxBio Inc. Novartis AG

Unit: USD/Billion

# ENX-201 Management Team



Yu-Fang Hu



Pieter J. Gaillard



Yuan-Yi Chou



# ENX-201 Scientific Advisory Board

蔡清標  
Taipei, Taiwan



THE UNIVERSITY OF  
SYDNEY



臺北榮民總醫院  
Taipei Veterans General Hospital



台灣神經學學會  
Taiwan Neurological Society

Olaf Stuve  
(Texas, USA)



**UT Southwestern**  
Medical Center



U.S. Department  
of Veterans Affairs

Ralf Linker  
(Erlangen, Germany)



UNI  
FREIBURG

UKRUB

UNIVERSITÄTSKLINIKUM DER  
RUHR-UNIVERSITÄT BOCHUM

Frederik Barkhof  
(Amsterdam, Netherlands)



**UCL**



VU University  
Medical Center  
Amsterdam

**TTV BIOPHARM**  
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**Manufacture Facilities**

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# Manufacture Facilities

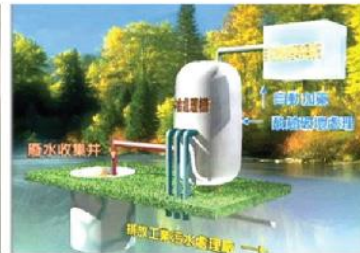
- The only PIC/S GMP certified manufacture sites for high potency oncology, we passed the following official inspections such as
  - EMEA by Hungary, Arabian, Jordan, Germany, Brazil, Japan.
  - USA FDA, Japan, EMA by Belgium, Turkey, Korea and Kazakhstan.
- High standard Validation of
  - Equipment qualification/ Laboratory instruments qualification/ HVAC system/ Water system/ Compressed air system/ Nitrogen system/ Cleaning/ Analytical method/ Process/ Computer/ Logistic
- Individual flow management
  - Air flow/ Man flow/ Material flow/ Product flow/ Waste flow
  - To prevent cross contamination and environmental pollution



HVAC System



Work Safety



Environmental Protection



# 中壢廠



# 六堵廠



- Comply with PIC/S GMP and Taiwan FDA inspection for **non-cytotoxic or non-hormone**



**TTY** BIOPHARM<sup>®</sup>  
台灣東洋藥品

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**In Progress Status**

**Biotech Success**

# Oncology/Successful Products for Global

TTY has successfully registered **47** oncology product licenses in **10** countries.

Country	UFur	Oxalip	Lipo-Dox	Irino	Asadin	Gemmis	Tynen	Epicin	Thado	Anazo	Folina	Sulfin	Algycon	Colimycin	Maxtam	Total
Thailand	1	1	1	1	1				1		1	1	1	1	1	11
Philippines			1	1	1			1		1		1	1			7
Vietnam	1	1	1		1	2	2		1							9
Hong Kong	1	1		1		2	2	3								10
Malaysia	1		1		1		1		1		1					6
Singapore				1												1
India	1															1
Sri Lanka										1						1
Guatemala			1													1
Colombia			1													1
Total	5	3	6	4	4	4	5	4	3	2	2	2	2	1	1	48

國際代工合作廠商擁有**Lipo-Dox**在美國(**Doxil**)及歐洲(**Caelyx**)之藥證。

# Successful Oncology Products

**Asadin**  
(伸定注射劑)



**TS-1**  
(愛斯萬膠囊)



**Epicin**  
(益彼欣注射液)



**Tynen**  
(汰能注射劑)



**Anazo**  
(安納柔膜衣錠)



**Gemmis**  
(建仕注射劑)



**Zobonic**  
(抑骨凍晶靜脈注射劑)



**Ivic**  
(癌微可膜衣錠)



**UFUR**  
(友復膠囊)



**Pexeda Inj.**  
(派癌休注射劑)



**Lipo-Dox**  
(力得微脂體注射劑)



**Painkyl**  
(平舒疼口頰溶片)



**Oxalip**  
(歐力普注射劑)



**Thado**  
(賽得膠囊)



**Irino**  
(益立諾)



**Lonsurf**  
(朗斯弗膜衣錠)



**Megest**  
(麥格斯口服懸液劑)



**Otril**  
(嘔速停靜脈注射劑)



**Folina**  
(芙琳亞錠)



# Successful Products of Intensive Care

**Brosym C+S**  
(博益欣)



**Lipo-AB**  
(立博黴)



**Colimycin**  
(克痢黴素注射劑)



**Cubicin**  
(救必辛注射劑)



**Flusine**  
(弗路欣錠)



**Exacin**  
(依克沙)



**Maxtam**  
(抑西每靈注射劑)



**Agrippal**  
(安爾保流感疫苗)





# Successful Healthcare Products

**Algitab**  
(艾胃逆服)



**Cepiro**  
(希比洛靜脈乾粉注射劑)



**Alginos**  
(胃逆舒)



**METACIN**  
(西腹黴素注射劑)



**BIO-CAL PLUS**  
(滋骨咀嚼錠)



**Sulfin**  
(速復利錠)



# R&D Investment 研究及臨床

Year	2013	2014	2015	2016	2017	2018
Revenue (NTD,000)	2,307,540	2,384,220	2,738,956	3,344,262	3,672,040	3,555,620
R&D Expense (NTD,000)	289,530	283,470	236,398	230,192	219,126	230,595
Total Staff	484	494	450	508	520	530
R&D Manpower	111	105	97	105	98	98
R&D Expense/ Revenue	12.55%	11.89%	8.63%	6.88%	5.97%	6.49%
R&D Total Staff	22.93%	21.26%	21.56%	20.67%	18.85%	18.49%

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**Manufacture Facilities**

**Successful Product Categories**

**In Progress Status**

**Financial Disclosure**

# 歷年財務報表 (個體)

NTD in Thousands

Item	2013		2014		2015		2016		2017		2018	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	2,292,163	100%	2,384,207	100%	2,738,956	100%	3,344,262	100%	3,672,040	100%	3,555,620	100%
Gross Profit	1,404,003	61%	1,411,875	59%	1,777,941	65%	2,217,286	66%	2,347,809	64%	2,308,242	65%
Operating Expenses	-1,121,548	-49%	-1,144,400	-48%	-1,035,412	-38%	-1,063,104	-32%	-1,135,595	-31%	-1,251,591	-34%
Operating Profit	282,455	12%	267,475	11%	742,529	27%	1,154,182	34%	1,212,214	33%	1,056,651	31%
Non-Operating Income and Expenses	413,685	18%	596,585	25%	705,211	26%	277,855	9%	351,484	10%	611,161	17%
Income before Tax	696,140	30%	864,060	36%	1,447,740	53%	1,432,037	43%	1,563,698	43%	1,667,812	48%
Net Income	587,440	26%	779,645	33%	1,211,018	44%	1,193,324	36%	1,344,731	37%	1,461,381	42%
<b>EPS</b>	<b>2.52</b>		<b>3.14</b>		<b>4.87</b>		<b>4.80</b>		<b>5.41</b>		<b>5.88</b>	

# 歷年財務報表 (合併)

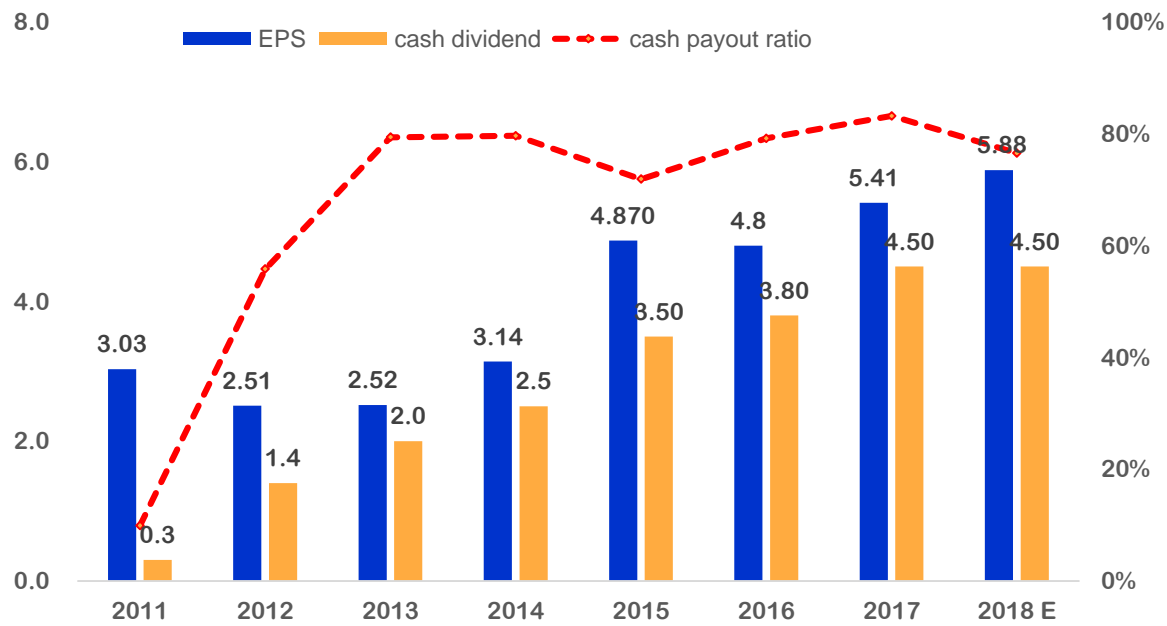
NTD in Thousands

Item	2015		2016		2017		2018		Q1/2019	
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	3,195,218	100%	3,760,717	100%	4,078,760	100%	4,036,196	100%	1,114,608	100%
Gross Profit	2,183,144	68%	2,559,220	68%	2,668,845	65%	2,663,179	65%	737,639	66%
Operating Expenses	-1,393,357	-44%	-1,379,533	-36%	-1,411,855	34%	-1,603,502	40%	-394,655	36%
Operating Profit	789,787	24%	1,179,687	32%	1,256,990	31%	1,059,677	25%	342,984	30%
Non-Operating Income and Expenses	735,808	23%	332,372	8%	338,077	8%	608,391	15%	33,042	4%
Income before Tax	1,525,595	47%	1,512,059	40%	1,595,067	39%	1,668,068	40%	376,026	34%
Net Income (Consolidated)	1,246,592	38%	1,254,724	33%	1,368,314	33%	1,462,299	35%	301,379	27%
Net Income (TTY)	1,211,018	37%	1,193,324	31%	1,344,731	32%	1,461,381	35%	293,779	26%
<b>EPS</b>	<b>4.87</b>		<b>4.80</b>		<b>5.41</b>		<b>5.88</b>		<b>1.18</b>	

# Dividend Payout 股息配發

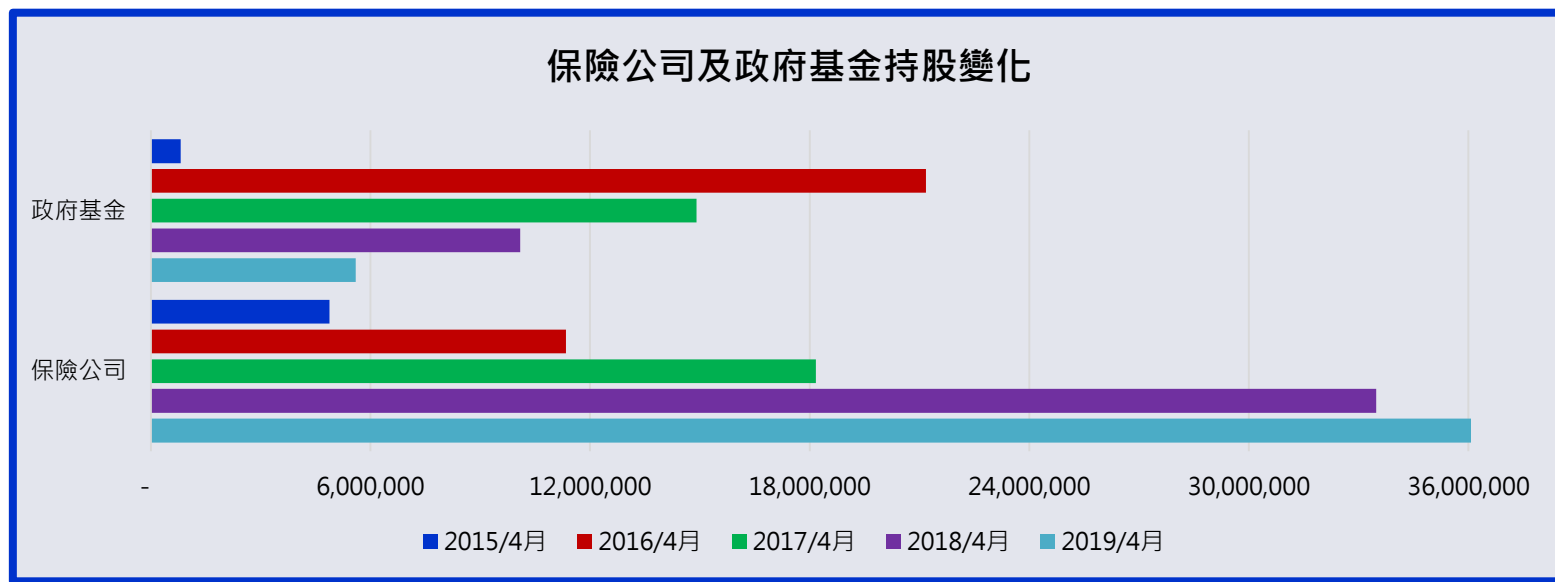
Item \ Year	2013	2014	2015	2016	2017	2018
Cash Payout Ratio	79.4%	79.6%	71.9%	79.2%	83.2%	76.5%
Total Dividend	2.67	2.50	3.50	3.80	4.50	4.50

Wait for approval by Annual General Meeting on 6/25/2019.



# 保險公司及政府基金持股

機構 \ 持股情形	2015/4月		2016/4月		2017/4月		2018/4月		2019/4月	
	持有股數	持股比例	持有股數	持股比例	持有股數	持股比例	持有股數	持股比例	持有股數	持股比例
保險公司	4,880,800	1.96%	11,339,000	4.56%	18,169,000	7.31%	33,474,000	13.46%	38,416,000	15.45%
政府基金	817,021	0.33%	21,177,843	8.52%	14,904,000	5.99%	10,088,843	4.07%	5,598,843	2.26%
合計	5,697,821	2.29%	32,516,843	13.08%	33,073,000	13.30%	43,562,843	17.53%	44,014,843	17.71%





Let's share and grow together  
in this big family



東生華製藥  
tsh biopharm



PharmaEngine

智擎生技製藥股份有限公司

