

### 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;
- 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 <u>Cancer</u>, <u>CNS</u>, <u>Autoimmune</u>, <u>Diabetes Mellitus</u> & <u>Infectious Diseases</u>.



# Agenda

**Company Overview Product Strategy Product Pipeline** Manufacture Facilities Successful Product Categories In Progress Status **Biotech Success** 

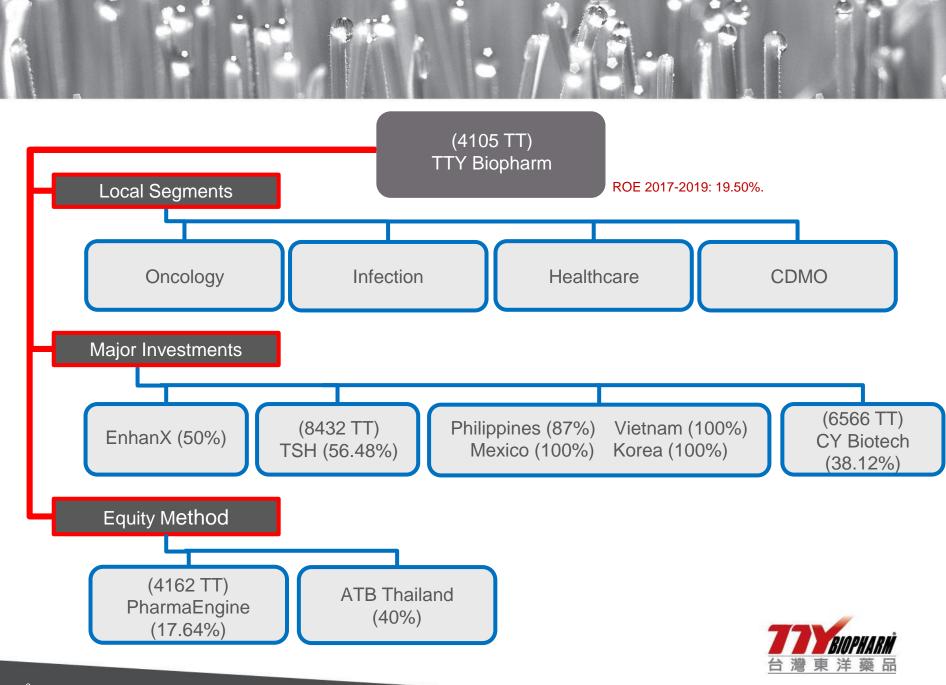


# **Company Overview**

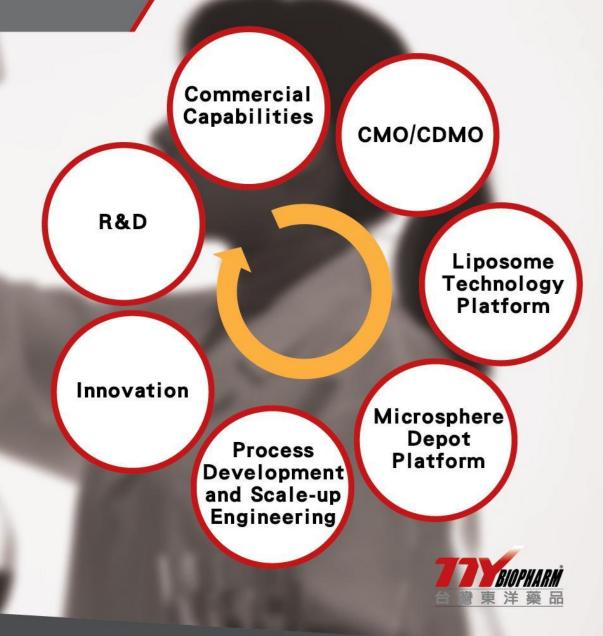


- Founded in 1960, restructured in 1996
- Traded in the Taiwan TPEx (2001, Code: 4105);
- Shares outstanding: 248.65 Million Shares (June, 2019)

- TTY Biopharm consolidated sales as of 2019- NTD 4.44B (USD 148M) 2018- NTD 4.04B (USD 131M)
- Headquarter: Taipei, Taiwan Number of employees: 554



# **TTY Core Competences**



# Agenda

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**Biotech Success** 



Products	World Market USD/M	Core Technology	Advantages		
Caelyx/Doxil	600	Pegylated Liposome Technology	Worldwide Manufacturing Patent		
Pegylipo		. ogjistes _poodo rodorgj	Tronding rate in		
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 Deport Platform		



# ENX-201 Pipeline

ENX-201: Liposomal Methylprednisolone Injection (glutathione PEGylated liposomal methylprednisolone)

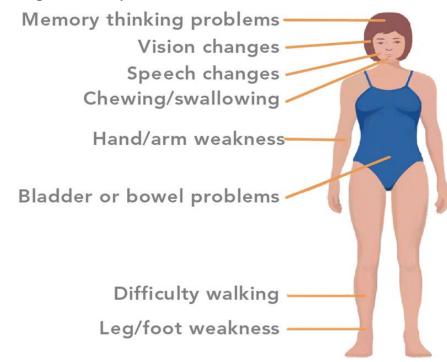
	201 <sup>4</sup> 201	2	017	20	)18	4	201	9	20	20		202	21	2022	2	20	23		202	24	
Phase I																					
Phase IIa																					
Scientific advice from FDA & EMA																					
Phase II/III in MS relapses (vs placebo)																					
Phase II/III in MS relapses (vs MP)																					
US NDA indication #1																					
EU MAA indication #1																					



### 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



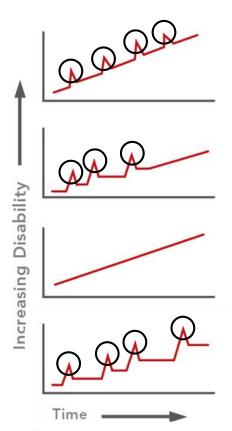
#### Whole body:

Fatigue
Coordination
Dizziness/poor balance
Muscle tightness
or stiffness
Numbness/tingling
Pain
Burning
Itching



### 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。



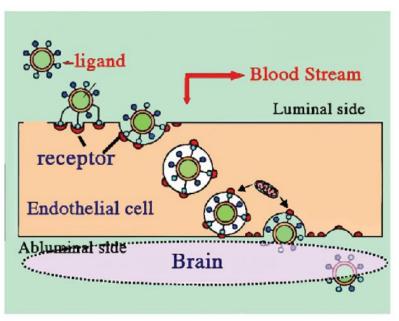
## Introduction of MS

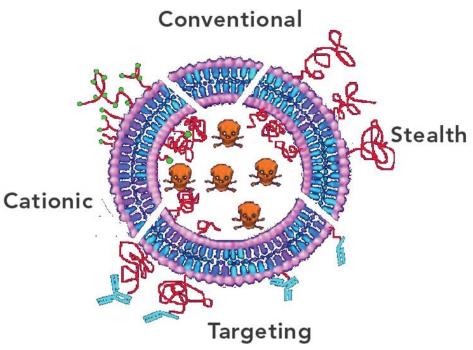
# World distribution of multiple sclerosis: greater prevalence in higher northern and southern latitudes



### **ENX-201 Introduction**

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



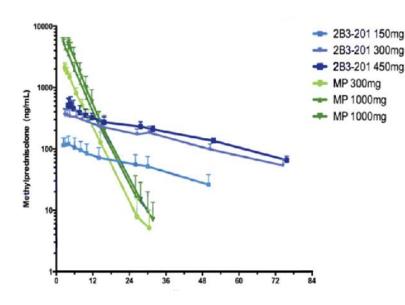




# Phase I Study (Solution)

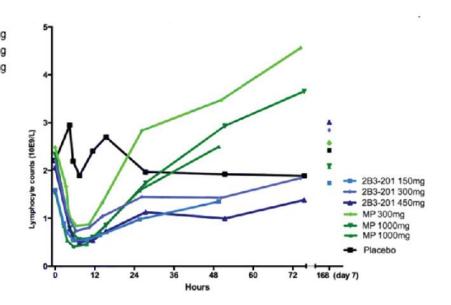
# Phase I dose-escalation results Pharmacokinetics

- 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

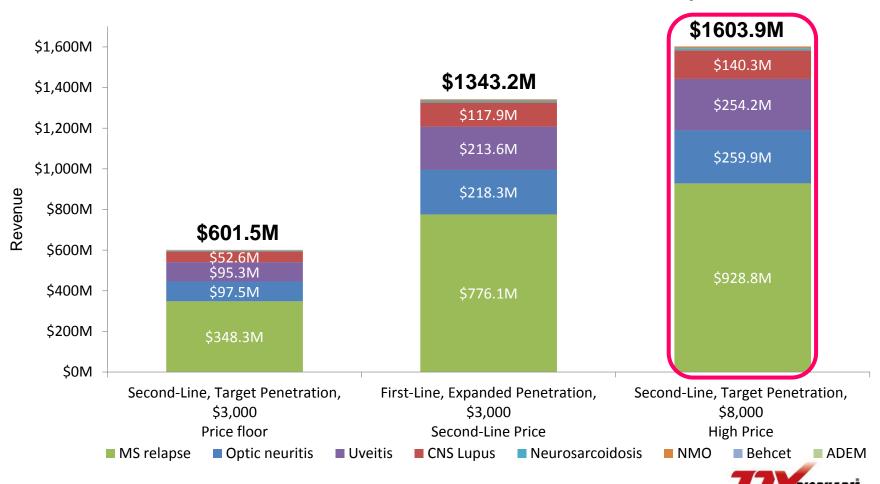
- Rapid and sustained immunosuppressive effect
- Lymphocyte count crossed baseline within 7 days in all groups





### **Potential Market Size**

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



## **ENX-201 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 <u>one-shot</u> intravenous injection which brings <u>home-care convenience</u> and <u>better tolerance</u> 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 EMDSerono 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



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Manufacture Facilities

**Successful Product Categories** 

In Progress Status

**Biotech Success** 



## **Successful Oncology Products**

UFUR (友復膠囊)



Lipo-Dox (力得微脂體 注射劑)



TS-1 (愛斯萬膠囊)



Lonsurf (朗斯弗膜衣錠)



Thado (賽得膠囊)

Gemmis (建仕注射液)



Zobonic (抑骨凍晶靜脈 注射劑)



lvic (癌微可膜衣錠)



Asadin (伸定注射劑)



Pexeda Inj. (派癌休注射劑)



Epicin (益彼欣注射液)



Painkyl (平舒疼口頰溶片)



Oxalip (歐力普注射劑)



Anazo (安納柔膜衣錠)



Irino (益立諾)



Tynen (汰能注射劑)



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)



Colimycin (克痢黴素注射劑)



Cubicin (救必辛注射劑)









Agrippal (安爾保流感疫苗)





## **Successful Healthcare Products**

Algitab (艾胃逆服)



Sulfin (速復利錠)



BIO-CAL PLUS (滋骨咀嚼錠)



METACIN (西腹黴素注射劑)



Alginos (胃逆舒)



Cepiro (希比洛靜脈乾粉 注射劑)





# R&D Investment 研究及臨床

Year Subject	2013	2014	2015	2016	2017	2018	2019
Revenue (NTD,000)	2,307,540	2,384,220	2,738,956	3,344,262	3,672,040	3,555,620	4,044,660
R&D Expense (NTD,000)	289,530	283,470	236,398	230,192	219,126	230,595	231,026
Total Staff	484	494	450	508	520	530	554
R&D Manpower	111	105	97	105	98	98	106
R&D Expense/ Revenue	12.55%	11.89%	8.63%	6.88%	5.97%	6.49%	5.70%
R&D Total Staff	22.93%	21.26%	21.56%	20.67%	18.85%	18.49%	19.13%



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**Financial Disclosure** 



# Financial Performance (Parent Company Only)

#### NTD in Thousands

ltem	2016		2017		2018		2019			
	Amount %		Amount	%	Amount	%	Amount	%		
Net Sales	3,344,262	100%	3,672,040	100%	3,555,620	100%	4,044,660	100%		
Gross Profit	2,217,286	66%	2,347,809	64%	2,308,242	65%	2,577,394	63%		
Operating Expenses	-1,063,104	-32%	-1,135,595	-31%	-1,251,591	-34%	-1,361,553	-34%		
Operating Profit	1,154,182	34%	1,212,214	33%	1,056,651	31%	1,215,841	29%		
Non-Operating Income and Expenses	277,855	9%	351,484	10%	611,161	17%	-33,172	-1%		
Income before Tax	1,432,037	43%	1,563,698	43%	1,667,812	48%	1,182,669	28%		
Net Income	1,193,324	36%	1,344,731	37%	1,461,381	42%	900,081	21%		
EPS	4.80		5.41		5.88		5.88		3.62	



# Financial Performance (Consolidated)

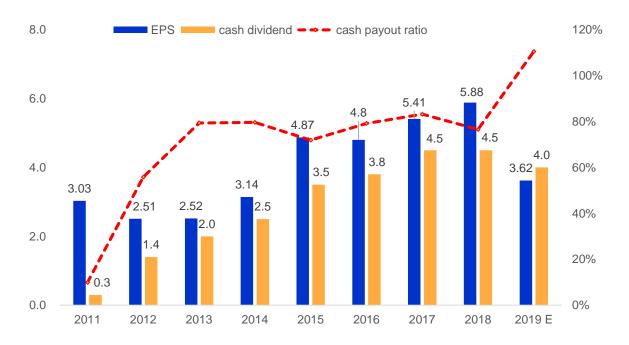
#### NTD in Thousands

Item	2016		2017		2018		2019		Q1/2020		
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%	
Net Sales	3,760,717	100%	4,078,760	100%	4,036,196	100%	4,466,308	100%	1,093,467	100%	
Gross Profit	2,559,220	68%	2,668,845	65%	2,663,179	65%	2,902,384	65%	707,411	65%	
Operating Expenses	-1,379,533	-36%	-1,411,855	34%	-1,603,502	40%	-1,673,775	37%	-423,670	39%	
Operating Profit	1,179,687	32%	1,256,990	31%	1,059,677	25%	1,228,609	28%	283,741	26%	
Non-Operating Income and Expenses	332,372	8%	338,077	8%	608,391	15%	-25,955	-0%	39,876	4%	
Income before Tax	1,512,059	40%	1,595,067	39%	1,668,068	40%	1,202,654	28%	323,617	30%	
Net Income (Consolidated)	1,254,724	33%	1,368,314	33%	1,462,299	35%	907,705	21%	259,241	24%	
Net Income (TTY)	1,193,324	31%	1,344,731	32%	1,461,381	35%	900,081	21%	253,571	23%	
EPS	4.80		5.41		5.88		3.62		1.02		



# **Dividend Payout**

Year	2013	2014	2015	2016	2017	2018	2019
Cash Payout Ratio	79.4%	79.6%	71.9%	79.2%	83.2%	76.5%	110.5%
Total Dividend	2.67	2.50	3.50	3.80	4.50	4.50	4.00





# Gov't Funds & Ins. Co.'s Holdings

Holdings Institution	April/2016	April/2017	April/2018	April/2019	April/2020
Insurance Company	4.56%	7.31%	13.46%	15.45%	13.82%
Government Funds	8.52%	5.99%	4.07%	2.26%	4.76%
Total	13.08%	13.30%	17.53%	17.71%	18.58%

