

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.





- ◆ 櫃買中心推動公司治理成 效卓著,台灣東洋亦遵循 主管機關規範,矢志成為 卓越公司治理企業。
- ◆ 台灣東洋之核心價值為公司治理及企業永續發展。
- ◆ 依據GRI標準編製企業社會 (CSR)責任書已3年。

連續**3**年, 榮獲台灣證交所公司治理評鑑上櫃公司**第一級距**。

選任 2 位女性董事,落實高階管理階層性別多元化。

董事開會 14次,平均出席率 92.06% (未含委託出席)。

獨立董事共 3位,占比 33.33%

2018 年度共參加 6 次海內外法人說明會及投資論壇。

自 2018 年起,設置誠信經營推動小組

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> & Infectious Diseases.

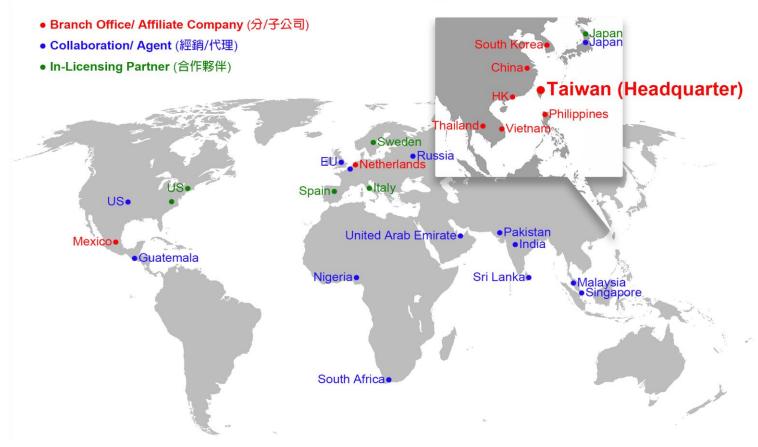


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Company Overview Product Strategy Product Pipeline Manufacture Facilities Successful Product Categories In Progress Status **Biotech Success**

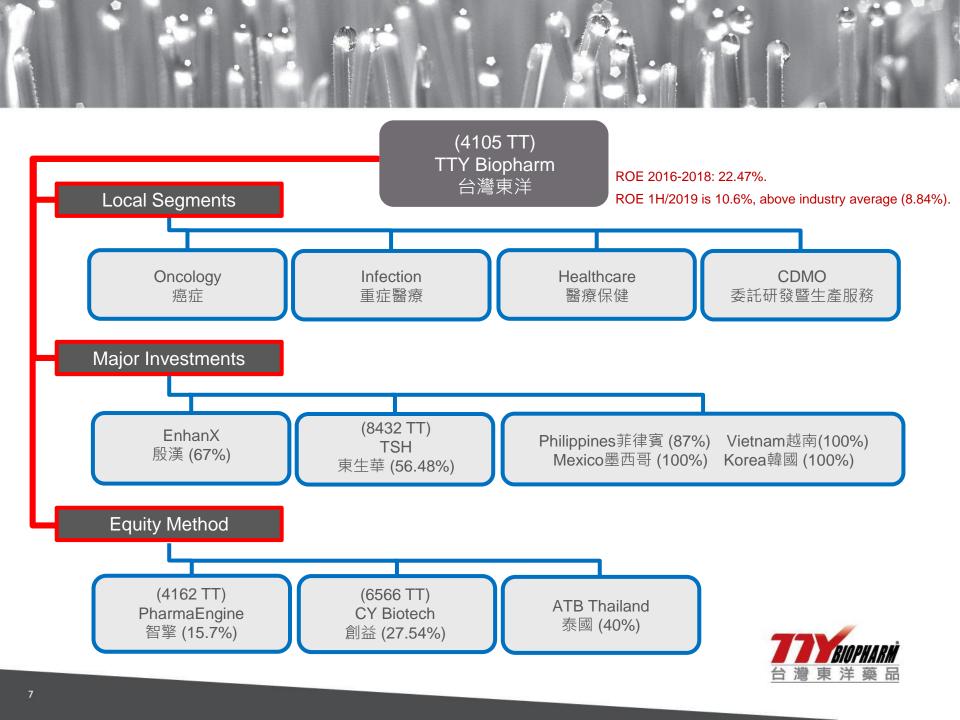


Company Overview



- 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 1H/2019- NTD 2.21B (USD 70M) 2018- NTD 4.04B (USD 131M)
- Headquarter: Taipei, Taiwan Number of employees: 530

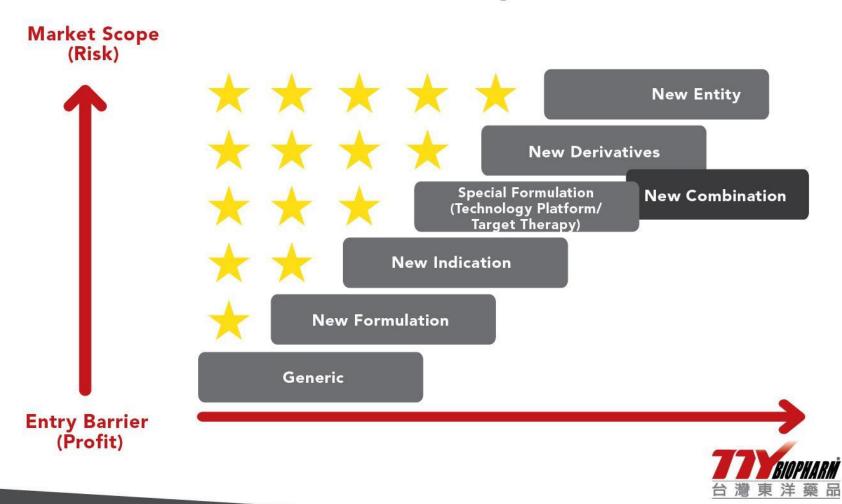


TTY 核心能力



Product Strategy

Trends for Pharmaceutical Industry



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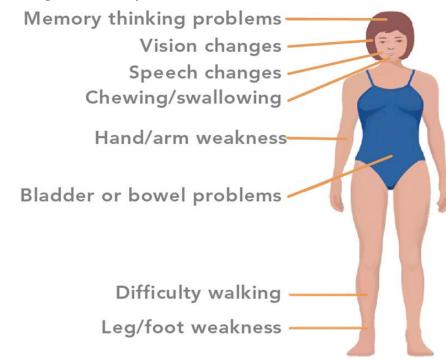
產品組合	World Market USD/M	核心技術	產品優勢
Caelyx/Doxil Pegylipo	600	Pegylated Liposome Technology	Worldwide Manufacturing Patent
Lipo-AB	440	Liposome Technology	Worldwide Manufacturing Patent
Octreotide	1,500	Microsphere Formulation	PLGA, Star Polymers Synthesized by TTY.
Colimycin	150	Formulation	First Choice 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 Deport 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



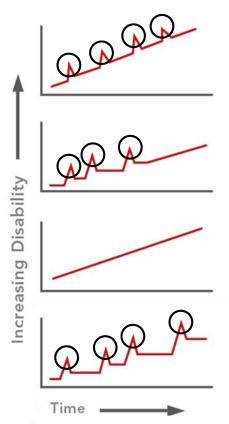
Whole body:

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。

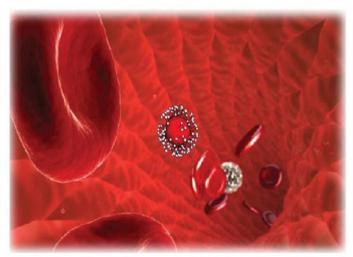


Introduction of MS

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

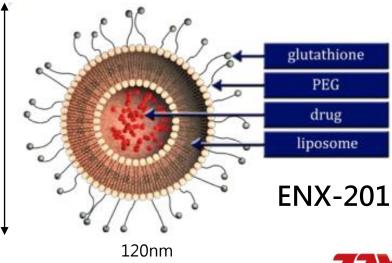


Introduction of the Product



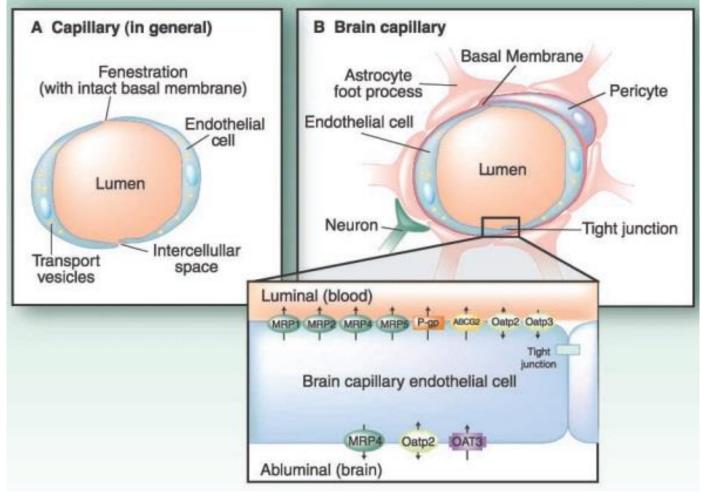
Targeting Liposomal Methylprednisolone Injection (glutathione PEGylated liposomal methylprednisolone) is being developed for patients suffering from acute and chronic neuro-inflammatory diseases, with an initial focus on patients with acute MS relapses.







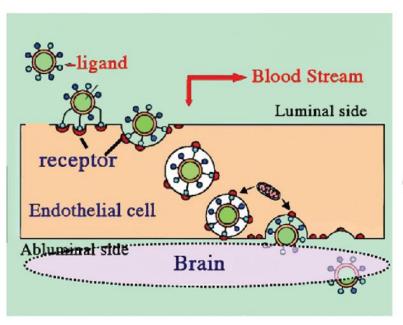
Introduction of BBB

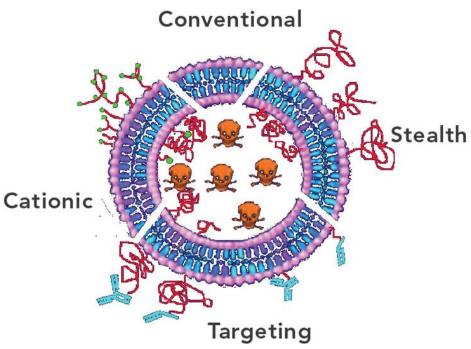




ENX-201 Introduction

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



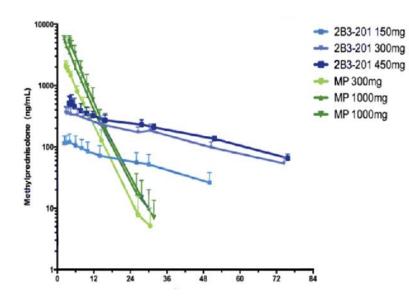




Phase I Study (Solution)

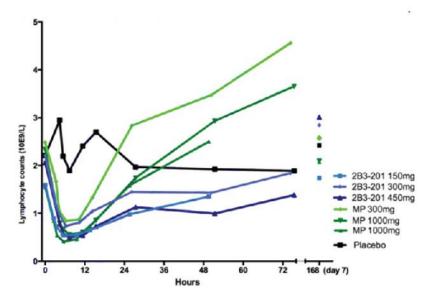
Phase I dose-escalation results Pharmacokinetics

- 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

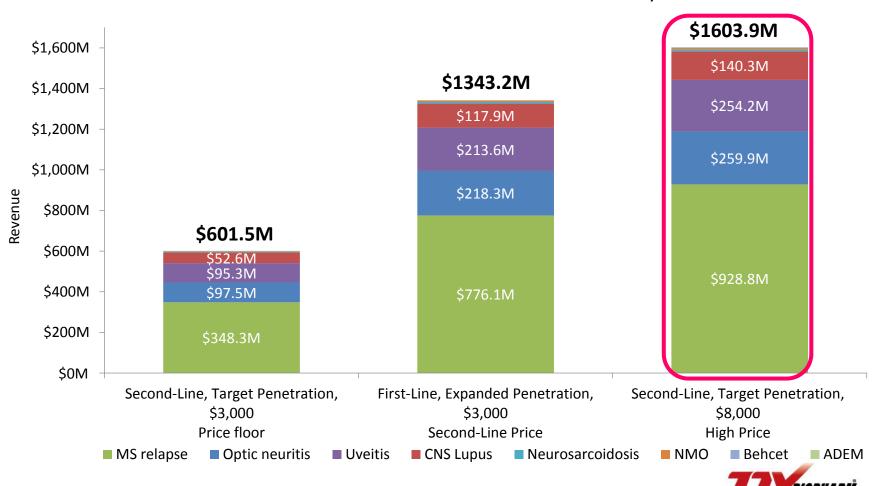
- Rapid and sustained immunosuppressive effect
- Lymphocyte count crossed baseline within 7 days in all groups





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 <u>one-shot</u> intravenous injection which brings <u>home-care convenience</u> and <u>better</u> <u>tolerance</u> to patients suffering acute multiple sclerosis relapses.



ENX-201 Pipelime

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

	2014 2016	2	017	202	18	20	19	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																			



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)	18	Shire Plc Nuo Therapeutics GlaxoSmithKline Plc Zymenex A/S RegenxBio Inc. Novartis AG

Unit: USD/Billion



ENX-201 Management Team















































ENX-201 Scientific Advisory Board















Olaf Stuve (Texas, USA)

UTSouthwestern Medical Center







Frederik Barkhof (Amsterdam, Netherlands)







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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

2013 / 2016 / 2019

2016







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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	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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Financial Disclosure



歷年財務報表(個體)

NTD in Thousands

Item	2015		2016		2017		2018		
	Amount	%	Amount	%	Amount	%	Amount	%	
Net Sales	2,738,956	100%	3,344,262	100%	3,672,040	100%	3,555,620	100%	
Gross Profit	1,777,941	65%	2,217,286	66%	2,347,809	64%	2,308,242	65%	
Operating Expenses	-1,035,412	-38%	-1,063,104	-32%	-1,135,595	-31%	-1,251,591	-34%	
Operating Profit	742,529	27%	1,154,182	34%	1,212,214	33%	1,056,651	31%	
Non-Operating Income and Expenses	705,211	26%	277,855	9%	351,484	10%	611,161	17%	
Income before Tax	1,447,740	53%	1,432,037	43%	1,563,698	43%	1,667,812	48%	
Net Income	1,211,018	44%	1,193,324	36%	1,344,731	37%	1,461,381	42%	
EPS	4.87		4.80		5.41		5.88		



歷年財務報表(合併)

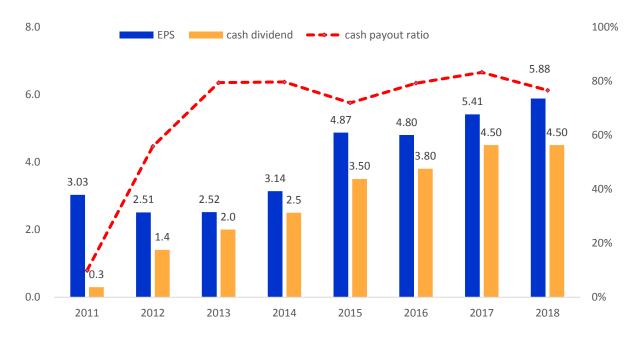
NTD in Thousands

ltem	2015		2016		2017		2018		1H/201	9
	Amount	%	Amount	%	Amount	%	Amount	%	Amount	%
Net Sales	3,195,218	100%	3,760,717	100%	4,078,760	100%	4,036,196	100%	2,205,525	100%
Gross Profit	2,183,144	68%	2,559,220	68%	2,668,845	65%	2,663,179	65%	1,437,619	65%
Operating Expenses	-1,393,357	-44%	-1,379,533	-36%	-1,411,855	34%	-1,603,502	40%	792,207	36%
Operating Profit	789,787	24%	1,179,687	32%	1,256,990	31%	1,059,677	25%	645,412	29%
Non-Operating Income and Expenses	735,808	23%	332,372	8%	338,077	8%	608,391	15%	64,600	3%
Income before Tax	1,525,595	47%	1,512,059	40%	1,595,067	39%	1,668,068	40%	710,012	32%
Net Income (Consolidated)	1,246,592	38%	1,254,724	33%	1,368,314	33%	1,462,299	35%	560,638	25%
Net Income (TTY)	1,211,018	37%	1,193,324	31%	1,344,731	32%	1,461,381	35%	552,645	25%
EPS	4.87		4.80		5.41		5.88		2.22	



Dividend Payout 股息配發

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





保險公司及政府基金持股

持股情形 機構	2015/4月	2016/4月	2017/4月	2018/4月	2019/4月
保險公司	1.96%	4.56%	7.31%	13.46%	15.45%
政府基金	0.33%	8.52%	5.99%	4.07%	2.26%
合計	2.29%	13.08%	13.30%	17.53%	17.71%





