# BIOPHARM 台灣東洋藥品

### WELCOME TO JOIN US

February, 2016

### **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.** 





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> & I<u>nfectious Diseases</u>.



### Agenda





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### **Company Overview**



- Founded in 1960, restructured in 1996
- Traded in the Taiwan TPEx

(2001, Code: 4105);

#### Shares outstanding: 248 Million Shares

(January, 2016)

TTY Biopharm consolidated sales as of

2015- NTD 3.20 Billion, USD 97.4 Million

### Headquarters: Taipei, Taiwan

Number of employees: 453





- TTY Biopharm is a global leader in Super-Generic Drugs and novel bio-drug development with strong growth potentials (targeting for 20% sales CAGR in 2014-19).
- TTY is Taiwan's largest biotechnology conglomerate with the most completed biotechnology products pipeline including oncology drugs, new formulations, ... etc.
- Market cap US\$634mn.
- Currently has three major subsidiaries: PharmaEngine (listed), market cap US\$819mn, 19.33% holding; TSH Biopharm (listed), market cap US\$60mn, 56.48% ownership; CY Biotech, 27.84% holding
- Shareholder value creation-
- TTY's ROE 17.9% in 2010-2014, ROE 18.1% in 2014 (above industry average 7.35%).
- TTY targets for 20% ROE in 2014-19.
- TTY aims to be a world-class biotechnology public listed company with multi-bn market capitalization in coming years.











### **TTY Core Competences**



### Agenda



### **Product Strategy**

**Product Pipeline** 

**Manufacture Facilities** 

Successful Product Categories

In Progress Status

**Biotech Success** 



### **Product Strategy**

### **Trends for Pharmaceutical Industry**



# **TTY Super Generics Pipeline**

Programs	Indication(s)	R&D (BE;BA+CT)	ANDA (EU/USA)
Caelyx/Doxil (Lipo-Dox)	Metastatic breast cancer BC \ AIDS-related Kaposi's sarcoma \		Approved
Caelyx II	Multiple myeloma, MM Ovarian cancer		
Lipo- Amphotericin B	Leishmaniasis Concurrent renal toxicity invasive The infected bursa meningitis HIV Systemic Fungal Infection		Filing (TW Approved)
Leuprolide Acetate Injection	Prostate Cancer S Management of Endometriosis S Uterine Fibroids S Central Precocious Puberty		Filing
Risperidone Injection	Schizophrenia		Filing
SPL206	Functional gastric, intestinal, pancreatic endocrine tumors		
LGIA10	Type II Diabetes Mellitus		



# **TTY Super Generics Pipeline**

Programs 產品組合	Indication(s) 適應症	World Market (USD est.)	Core Technology 核心技術	Advantages 產品優勢
Caelyx/Doxil (Lipo-Dox)	Metastatic breast cancer BC AIDS-related Kaposi's sarcoma Multiple myeloma, MM Ovarian cancer	6E	Pegylated Liposome Technology	Worldwide manufacturing patent
Lipo- Amphotericin B	Systemic Fungal Infection	4.4E	Liposome Technology	Worldwide manufacturing patent
Leuprolide Acetate Injection	Prostate Cancer > Management of Endometriosis > Uterine Fibroids > Central Precocious Puberty	12.4E	Lupron Depot Microsphere Formulation	Worldwide manufacturing patent
Risperidone Injection	Schizophrenia	9.6E	Microsphere Formulation	Worldwide manufacturing patent
SPL206	Functional gastric, intestinal, pancreatic endocrine tumors	15E	Microsphere Formulation	PLGA used for particular star polymers synthesized by TTY.
LGIA10	Type II Diabetes Mellitus	9.1E	Microsphere Formulation	Worldwide manufacturing patent Microsphere Depot Platform



### **Specialties- Caelyx®/Doxil®**

#### Caelyx®/Doxil® (Doxorubicin HCl Injection)

**Liposome:** A tiny bubble that can be filled with drugs and carry drugs into tissues.

How does liposome treat cancer? Healthy human blood vessels are encapsulated by endothelial cells which are bounded by tight junctions (BBB->Blood Brain Barrier). Tight junctions will stop large particles like liposome leaking out of the vessel.

Tumor vessels do not have tight junctions. Therefore, liposomes can penetrate tumor cells from the blood but blocked out by endothelial wall of healthy cells. In another word, liposome can "target" tumors by nature.





Source: Asia Pacific Equity Research, March 4<sup>th</sup>, 2011, JP Morgan

100 nm







Source: 2011 Evaluate Pharma report; +2008 WHO report















### **Specialty- Leuprolide Acetate Injection**

#### Schedule for launch:

- EU- 2016 est.
- USA- 2018



Table 4-5 World Hormone Therapy Market Estimated Products Sales by Cancer Type, 2008 (in million of dollars at the manufacturers level)

Cancer Type	Revenues Estimates	% of Market	Number of top Active Ingredients*
Breast	\$5,073	55.6	7
Prostate	4,032	44.2	4
Others	20	0.2	0
Prostate	\$9,125	100	10

active ingredients with combined sales exceeding \$100 million annually.

Source: Kalorama Information: (Cancer Therapeutics and Biotherapeutics 2009)



### **Specialty- Risperidone Injection**

#### Indication: Schizophrenia 皮质银体 Global market: USD\$960 Million 神经光 Ν 25.88 0 Risperidone 10 10 10 10 3.5 Beagle in vivo release Risperidone 9-OH-Risperidone --Risperdal Consta\_AKZT800 50 14 -RPO\_120523 -RPO 120523 12 9-OH-Risperidone (ng/ml) 40 Risperidone (ng/ml) 10 30 8 6 20 10 20 Time (days) 20 30 Time (days) 30 50 10 40 50 10

## **Specialty-SPL206**

### Indications:

- Acromegaly
- Severe diarrhea/flushing episodes associated with metastatic carcinoid tumors
- Profuse watery diarrhea associated with VIP-secreting tumors

#### Synthesized by TTY

#### TTY synthetic star polymers as a carrier!!



### **Mechanism of SPL206**





# Mechanism of Action (SPL206)



Somatostatin binds to somatostatin receptors (SSTR), exert a variety of physiological effects on various tissues, organs. SSTR has five subtypes (SSTR1 ~ 5), the binding affinity of octreo-tide varies depending on the sub-type, high in the order of SSTR2> SSTR5> SSTR3

Octreotide is presumed to bind to SSTR present on the cells of the pituitary adenoma and gastrointestinal hormone-producing tumor, VIP, it suppresses the secretion of gastrointestinal hormones and GH of gastrin.



# **Specialty-LGIA10**

#### The Role of Incretins (GLP-1 and GIP) in Glucose Control





### **Mechanism of LGIA10**

#### DPP-4 Inhibition: A Means to Achieve Enhancement of Intact Incretins

In vitro and in vivo DPP-4 inhibition increases levels of intact incretins (GLP-1 and GIP). <sup>1-3,5,15</sup>





## Mechanism of LGIA10

### GLP-1 and Diabetes Indication: Type II Diabetes Mellitus



### Mechanism of LGIA10

#### **DPP-4** Inhibitors Enhance Incretin and Insulin Secretion



Adapted from: Barnett A. Int J Clin Pract 2006;60:1454-70 Drucker DJ, Nauck MA. Nature 2006;368:1696-705 Idris I, Donnelly R. Diabetes Obes Metab 2007;9:153-65



### **TTY Product Pipeline**

#### Liposomal Methylprednisolone Injection in Multiple Sclerosis Milestone stages and Clinical Timelines

	20	15			20	16			20	17			20	18			20	19			20	20	
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### Agenda

**Company Overview** 

**Product Strategy** 

**Product Pipeline** 

### **Manufacture Facilities**

Successful Product Categories

In Progress Status

**Biotech Success** 



### **Manufacture Facilities**

- The only PIC/S GMP certified manufacture sites for high potency oncology, 2008/2013 EMA, 2010 Japan, 2013 US FDA, 2013 Brazil, Australia
- 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** 





### **Chungli Factory**

Chungli factory, total 6,347 square meters of land area. Four independent buildings (B, C, D, M)

#### **Building B**

1F: Oncology injection plant(B1)2F: Reconstruct planning undergoing3F: Water systemB1: P/M, F/P warehouse

#### **Building C**

1F: Oncology oral drug plant(C1), Office2F: HVAC, Logistic warehouse

Building D QC laboratory

Building D External-use plant





# Lioudu Factory





1124m<sup>2</sup> Production area of Each floor

8F法定留楼室	7F	Power
7F Warehouse	, <sup>7M</sup> Reserved	Fower
6F 5,7F office area	5F	Reserved
5F包裝·半成品倉	Dual Chamber & Prefilled syringe	洗衣中心
4F微生物實驗室	3F	A/C
	Microsphere	₩ A/C
2F	1F 2 <sup>nd</sup> Lyophilizer	<b>慰空、真</b> 3
1F Lobby	Lyophilized and Liquid Inj.	PW
B1F 消防水箱		-



### **Inspection Certificates**

#### PMDA (Japan)

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#### **FDA**

INFARTMENT OF HEALTH AND HUMAN SERVICES. Ľ

SUPPLEMENT APPROVAL

Food and Desig Administration Silver Spring MID (2000)

Janssen Products, L.P., Anartikon Metricos Science Assenciato Director, Fibbeld Regulatory Affilias 920 Rome 202 Scient F.O. Huo 302 Rathan, N. 05869

Dear Mr. Sourato

NDA 507185-046

Please refer to your Supplemental New Drug Application (NDA) dated July 12, 2015, received July 12, 2015, submitted under sortion 303(b) of the Foderal Food, Drug, and Cosmeric Ael (PDEA) for Teased (account on RC) Tayowine regression, 2010mg/10 ml and 80 mg/25 ml.

We aconowiedge second of your amendments to this supplement crited August 16, 2013, August 28, 2013, September 22, 2014, October 1, 2014, January 0, 2015, January 16, 2015, January 20, 2015, January 2015, January 20, 2015, Janua

The September 22, 2014, submission constituted a complete response to our November 12, 2013. Complete Response network (Sec.

This Price Anneoval supplemental new drug application provides for:

- a new computation of e. TTY Biopharm Company Londed (TTY Biopharm) located in Changli, Taoyeae, Taiven, R.O.C. for the manufacturing of the drug product;
- in charge in batch size of the drug product to  $60~\mathrm{L}$  and drug product manufacturing a new pre-sterilized, pre-siliconized stopper for the drug product container/closure
- . addition of a secondary metaorine site at Andersonliceron. Inc :
- rayisans of the package insert to conform with the requirements of context and format of labeling as described in 21 CFR 201.55 and 201.57, and the Programmy and Electrician Labeling Rule (PLLR); and,
- revisions of carton and immediate container labeling to mitigate the risk of madication errors

#### **EMA**



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

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### Agenda

### **Company Overview**

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### **Product Strategy**

**Product Pipeline** 

**Manufacture Facilities** 

### **Successful Product Categories**

In Progress Status

**Biotech Success** 



### Successful Products (Oncology, Taiwan & Segment Market)

Products 產品名稱	Indications 適應症	Market(s) 行銷地區
Asadin (伸定注射劑)	Acute promyelocytic leukemia, APL (急性前骨髓細胞白血病)	Taiwan ` Thailand ` Malaysia ` Philippine ` Vietnam
Gemmis (健仕注射液) Semmis	inoperable, locally-advanced (stage IIIa or IIIb) or Metastatic (stage IV) Non-small cell lung cancer (非小細胞肺癌) Inoperable (stage II or III) or metastatic (stage IV) Pancreatic cancer, PC (胰臟癌) Metastatic (stage IV) Urinary bladder cancer, UBC (膀胱癌) Metastatic (stage IV) Breast cancer , BC (轉移性乳癌) Recurrent (stage IV) Ovarian cancer, OC (卵巢癌)	Taiwan \ Vietnam \ Malaysia \ Sri Lanka \ Nigeria
Lipo-Dox (力得微脂體注射劑) CC LIPO-DOX	AIDS-related Kaposi's sarcoma in patients with low CD4 counts and extensive mucocutaneous or visceral disease. (愛滋病引發之卡波西氏肉瘤) Metastasis carcinoma of the ovary with recurrent to both first line platinum- and paclitaxel-based chemotherapy regimens (復發性卵巢癌) Metastatic (stage IV) Breast cancer, BC (轉移性乳癌) Combination with bortezomib in 2nd line multiple myeloma, MM (多發性骨髓瘤)	Taiwan ∖ Thailand ∖ Vietnam ∖ Sri Lanka
TS-1 (愛斯萬膠囊) 🔗	Gastric cancer, GC (胃癌): Stage II & III gastric cancer adjuvant treatment; Advanced gastric cancer (stage IV); Pancreatic cancer, PC (胰臟癌)	Taiwan 🤉 China
Zobonic (抑骨凍晶靜脈注射劑)	Multiple myeloma, MM (多發性骨髓瘤) Hypercalcemia of malignancy (惡性腫瘤之高血鈣併發症)	Taiwan
Painkyl Fentanyl(平舒疼口 頰溶片)	Breakthrough Pain (癌症突發性疼痛)	Taiwan Restricted Drug
Epicin 益彼欣*** Epicin	Oral Mucositis (頭頸癌&HSCT患者口腔潰爛疼痛)	Taiwan Restricted Drug
lvic® (癌微可) <mark>№℃癌微可</mark>	CML (慢性骨隨性白血病)	Taiwan



### Successful Products (Oncology, Taiwan & Segment Market)

Products 產品名稱	Indications 適應症	Market(s) 行銷地區
Oxalip (歐力普注射劑)	Colorectal cancer, CRC (結腸直腸癌): stage III colon cancer adjuvant treatment; Metastatic colorectal cancer (stage IV) Gastric cancer, GC (胃癌): Advanced gastric cancer (stage IV)	Taiwan ` Thailand ` Vietnam ` Singapore ` Nigeria ` Sri Lanka
Tynen (汰能注射劑)	Adjuvant & metastatic (lymph node positive) (stage II~IV) Breast cancer, BC (乳癌) Metastatic (stage IV) Non-small cell lung cancer (非小細胞肺癌) Hormone refractory metastatic prostate cancer, PC (前列腺癌) Locally advanced(stage III~stage IVB) squamous cell carcinoma of the head and neck (局部晩期頭頸部癌) Metastatic (stage IV) Gastric gland cancer (胃腺癌)	Taiwan ` Austria ` Germany ` Sweden ` Other EU members `
UFUR (友復膠囊)	Gastric cancer, GC (胃癌)- Adjuvant Treatment for stage IB, II, III patients after curative surgery; advanced gastric cancer (Stage IV) Colorectal cancer, CRC (大腸結腸直腸癌)- Stage II & III colorectal cancer; metastatic colorectal cancer (stage IV) Breast cancer, BC (乳癌), stage II breast cancer; Metastatic breast cancer (stage IV) Lung cancer, LC (肺癌) stage IB; Metastatic lung cancer (stage IV) Head & Neck cancer (頭頸癌), stage I to IV	Taiwan ` Thailand ` Vietnam ` Malaysia ` India ` Pakistan
Thado (賽得膠囊) <u>Thado</u>	Newly diagnosed multiple myeloma, MM (多發性骨髓瘤) Erythema Nodosum Leprosum, ENL (痲瘋性結節性紅斑)	Taiwan ` Philippines ` Malaysia



#### TTY has successfully registered 62 oncology product licenses in 17 countries.

	Country	UFUR	Oxalip	[Lipo-Dox]	lrino	Asadin	Gemmis	Tynen	Epicin	Thado	Anazo	Folina	Total
	Belgium							3					3
	Czech Republic							4					4
EU	Portugal						1						1
	Spain				2								2
	Austria							4					4
	Thailiand	1	1	1	1	1						1	6
	Philippines			1							1		2
	Vietnam	1	1	1	2	1	2			1	1		10
	Hong Kong	1	1		1		2	2	3				10
Asia	Malaysia	1	1			1	1	1		1		1	7
7 (5)(4	Singapore				1								1
	India	1											1
	Sri Lanka			1	1		1				1		4
	Pakistan	1											1
	Jordan				1								1
America	Costa Rica				1		1		1				3
Africa	Nigeria				1		1						2
	Total	6	4	4	11	3	9	14	4	2	3	2	62



### Successful Products (Anti-Infectives, Taiwan & Segment Market)

Products 產品名稱	Indications 適應症	Market(s) 行銷地區
Cubicin (救必辛注射劑) CubiCIN CUBICIN BEST for MRSA	<ol> <li>Complicated Skin and Skin Structure Infections caused by susceptible isolates of the following Gram-positive bacteria (治療下列感受性革蘭氏陽性菌引起的複雜 性皮膚和皮膚組織感染 (cSSSI)如下): Staphylococcus aureus (including methicillin- resistant isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae subsp. equisimilis, and Enterococcus faecalis (vancomycin-susceptible isolates only)</li> <li>Staphylococcus aureus Bloodstream Infections (Bacteremia), Including Those with Right-Sided Infective Endocarditis, Caused by Methicillin-Susceptible and Methicillin-Resistant Isolates (引起之血液感染(菌血症)包括由具methicillin感受性 及抗藥性菌株造成之右側感染性心內膜炎)</li> </ol>	Taiwan
	<ol> <li>利時曼氏病leishmaniasis又稱黑熱病Kala-azar</li> <li>骨髓移植後併發腎毒性侵入性細菌感染Concurrent renal toxicity invasive bacterial infection</li> <li>感染囊球菌腦膜炎的HIV患者The infected bursa meningitis HIV patients</li> </ol>	Global(2016/7) Taiwan
C+S (博益欣) Brosymer HEST for ency shall be	為一抗感染新療效複方新藥對鮑氏不動桿菌(AB菌)治療效果更佳,目前市場尚無 cefoperazone/sulbactam複方製劑,上市後可實際提供臨床用藥選擇性實際藥價低 於單方用藥,減低醫療浪費	Taiwan



### **Anti-Infectives Portfolio**

	Categories 類別	Products 產品	Indications 適應症	Stages 開發階段
1	抗細菌	Cubicin	G (+)	現有產品
2		CMS	G (-)	現有產品
3		Exacin	G (-)	現有產品
4		Brosym	Broad spectrum	現有產品
5		New formulated colistin	Anti-carbapenem resistant	Formulation
6		New cephalosporin	Broad spectrum	評估授權
7	抗黴菌	Lipo-AB	Broad spectrum	現有產品
8		Flusine	Cryptococcus and Candida	現有產品
9	Anti-HIV	DL7014 and TL7014	HIV	Formulation
10	Niche generic and TNCE	Antibiotics, Antifungals, Anti-virus	TBD	爭取經銷及自行開發



### R&D Investment 研究及臨床

Subject	Year	2007	2008	2009	2010	2011	2012	2013	2014	2015/1H
*D&C Resource 營收為 總公司+分 公司	Revenue (NTD,000)	1,519,680	1,773,420	2,067,360	1,786,500	2,098,500	2,158,500	2,307,540	2,384,220	1,196,780
	R&D Expense (NTD,000)	197,550	200,040	238,650	290,040	384,360	366,750	289,530	283,470	126,312
	Total Staff	319	339	400	338	374	404	484	494	471
	R&D Manpower	82	92	90	94	97	104	111	105	102
	R&D Expense/ Revenue	13.00%	11.30%	11.50%	16.20%	18.30%	16.90%	12.55%	11.89%	10.55%
	R&D Total Staff	25.70%	27.10%	22.50%	27.80%	25.90%	25.70%	22.93%	21.26%	21.66%

- Continuous investment in development & clinical research:
  - Strong product portfolio
  - Long product life cycle
  - Abundant Asian clinical data



### Agenda

**Company Overview** 

**Product Strategy** 

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Successful Product Categories

**In Progress Status** 

**Biotech Success** 



# **Registration Approval Status**

	送件日期 Apply	領證日期 Approval	中文品名	英文品名	核可類別	NPD Code
1	2011/09/27	2013/07/05	立博黴微脂粒凍晶乾粉 注射劑	Lipo-AB for Injection	監視期滿學名藥	LAIA98
2	2012/05/24	2013/02/08	佇骨濃縮注射液 4毫克/5毫升	Zobonic Concentrate for Solution for Infusion 4mg/5ml	新單位含量新藥	ZLIA08
3	2012/06/29	2014/02/19	博益欣注射劑	Brosym for Injection	新複方新藥	CSIA05
4	2013/06/13	2014/06/09	癌微可膜衣錠100毫克	lvic Film-Coated Tablets 100mg	監視期滿學名藥	IM7011
5	2013/03/29	預估 2016/03/31 前核准	霈力微脂粒注射劑	Pegylipo Liposomal Injection 2 mg/mL	監視期滿學名藥	LDIA09
6	2014/05/14	2015/01/20	派癌休注射劑	Pexeda Injection	新劑型新藥	PD8011
7	2014/08/07	預估 2016/03/31 前核准	癒復達注射液 50毫克/毫升	Fupadine Injection 50mg/ml	非監視學名藥	FR8013
8	2014/11/27	預估 2016 前核准	瑞伏駭膠囊 25毫克	Levlimide Capsules 25 mg	監視學名藥	LN9012



### Agenda

### **Company Overview**

**Product Strategy** 

**Product Pipeline** 

**Manufacture Facilities** 

Successful Product Categories

In Progress Status

#### **Biotech Success**



### Biotech Success Strategy (2016-2020)

### Marketing Development

- Liposome Doxorubicin into global peak sale
- TS-1 ` Painkyl ` Brosym(C+S) ` Aplidin into Peak sale
- Liposome Amphotericin B
- Risperidone PLGA
- Leuprolide Depot
- Regional markets integration
- Thailand ABT IPO

### • R&D

- CMO/CDMO
- PLGA(Microsphere) Development
- 1-2 NCE/NBE Projects
- Dual-Chamber-Filling System ready

<u>Complete listing for global</u> (Including China market)





