

#### **Third Quarter 2017 On-Line Investor Meeting**

#### November 06, 2017



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# **Overall Updates of ScinoPharm**

#### **Business Overview**

- Company specializes in high potency (steroid/cytotoxic) APIs and is expanding into sterile/aseptic injectable formulations
- Facility & organization established in Taiwan and expanding in China with a new GMP plant in Changshu & marketing base in Shanghai
- 73 generic APIs in current portfolio with 25 APIs launched; 55 US DMFs filed (764 DMFs WW), 33 US DMFs in oncology APIs. 100+ NCE CRAM projects, with 6 APIs launched and 4 in phase III for NDA filing in 1-3 years
- Fully compliant with world-class cGMPs and international regulatory requirements; Certified by US FDA, EMA, EDQM, Australian TGA, Japanese PMDA



#### **Driving Long Term Growth by Dual Profits**

#### Self-Developed Products

- Target difficult-to-make (peptide)API in our portfolio
- Tap into formulation business related to our API core competencies
- ✓ Target 505(b)(2) and Paragraph IV drug product via strategic alliances

Contract Services

- ✓ Provide CRO/CMO for APIs
- Offer integrated service from API to formulation for niche injectables
- Provide biologics fill & finish contract manufacturing services



### **Recap of Performances and Major Events**

- Reported the consolidated revenues for 3Q17 were NT\$849 million, net profits after-tax were NT\$ 107 million, gross margin was 48%, EPS was NT\$0.14
- The performances were mainly suffered by the unfavorable sales volumes and product mix of generic products in 3Q. However, CRAM business started to gain momentum and contributed to gross margin
- Passed Mexican healthy authority(COFEPRIS) inspection in Taiwan
- Passed Jiangsu FDA inspection in Changshu site
- On schedule to complete equipment assembly & verification in inhouse injectable plant. Planned to kick-off registration batch production for prefilled syringe by early 2018



# Financial & Operating Results 3Q, 2017

### **Quarterly P&L - Consolidated**

In NT\$ million, except for EPS	3Q,'17 (Reviewed)	2Q,'17 (Reviewed)	3Q,'16 (Reviewed)	QoQ	ΥοΥ
Operating Revenue	849	853	992	-1%	-14%
Gross Profit	407	326	466	25%	-13%
Gross margin	48%	38%	47%		
Operating Expenses	(256)	(239)	(233)	-7%	-10%
Operating Income	152	86	233	75%	-35%
Operating margin	18%	10%	24%		
Other Rev.(Exp.)	(25)	(7)	(27)	-252%	7%
Net Income before Tax	127	79	207	60%	-39%
Net Income after Tax	107	84	166	27%	-35%
Net margin after tax	13%	10%	17%		
EPS (after tax)	0.14	0.11	0.21		



### **Cumulative P&L - Consolidated**

In NT\$ million, except for EPS	1Q~3Q,'17 (Reviewed)	1Q~3Q,'16 (Reviewed)	ΥοΥ
Operating Revenue	2,621	3,028	-13%
Gross Profit	1,203	1,362	-12%
Gross margin	46%	45%	
Operating Expenses	(744)	(704)	-6%
Operating Income	459	658	-30%
Operating margin	17%	22%	·
Other Rev.(Exp.)	(61)	(60)	-1%
Net Income before Tax	398	598	-33%
Net Income after Tax	362	512	-29%
Net margin after tax	14%	17%	
EPS (after tax)	0.46	0.65	]



## **Balance Sheet - Consolidated**

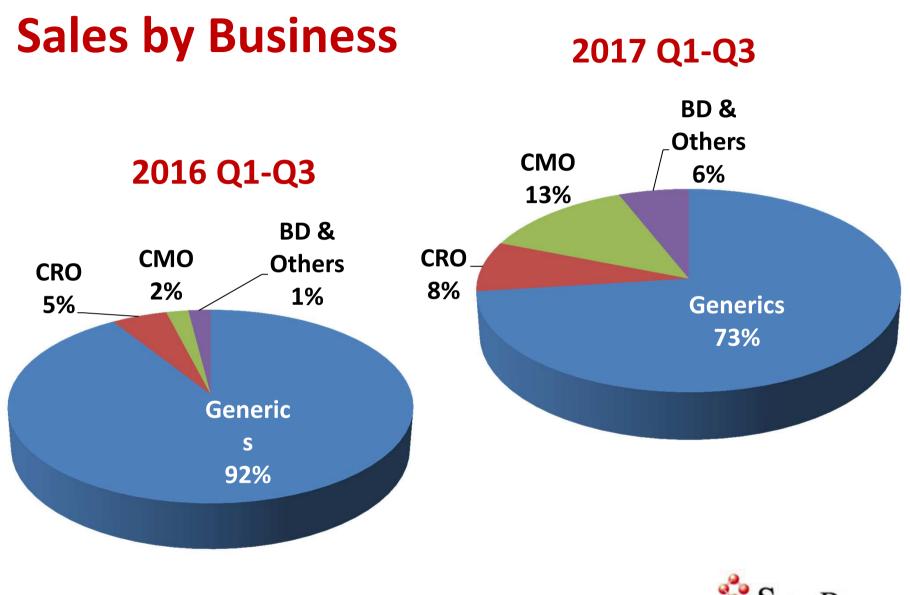
In NT\$ million	2017/09/30 (Reviewed)		2016/09/30 (Reviewed)	
Cash and Cash Equivalents	3,950	31%	3,137	25%
Accounts Receivable	470	4%	614	5%
Inventories	1,830	14%	2,018	16%
Long-Term Investments	391	3%	364	3%
Property, plant and equipment	5,122	40%	5,248	42%
Other Current/Non-Current Assets	1,107	8%	1,128	9%
Total Assets	12,870	100%	12,509	100%
Current Liabilities	1,219	10%	1,534	12%
L-T Liabilities and Others	1,300	10%	880	7%
Stockholders' Equities	10,351	80%	10,095	81%



### **Cash Flows - Consolidated**

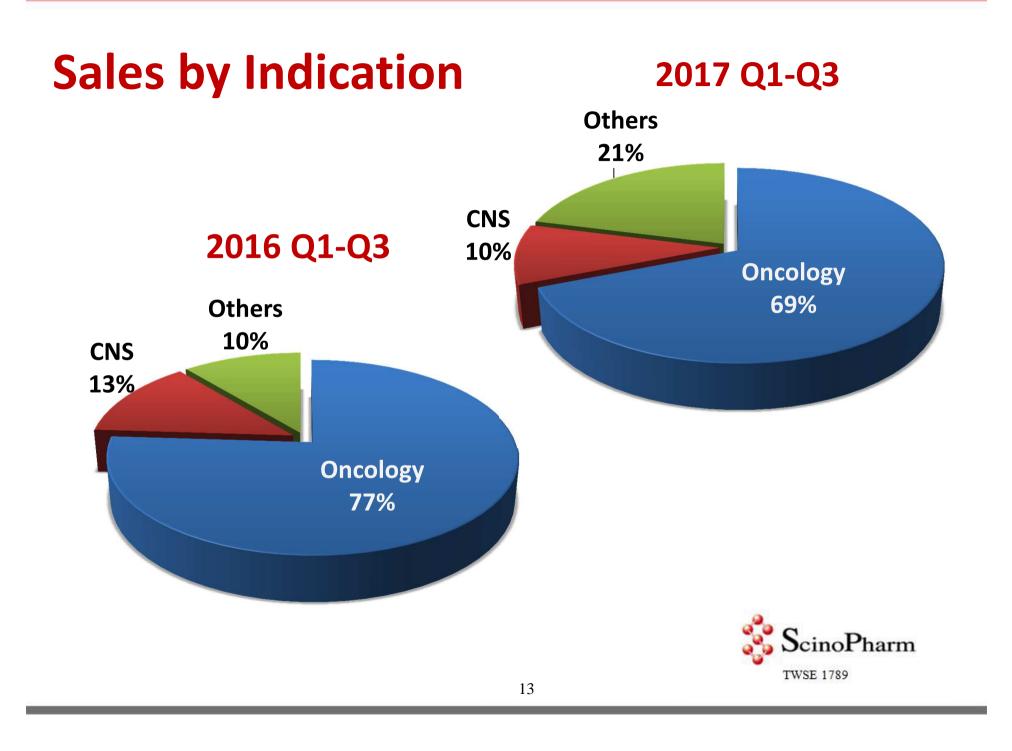
In NT\$ million	1Q~3Q 2017 (Reviewed)	1Q~3Q 2016 (Reviewed)
Cash and cash equivalents at beginning of period	3,707	2,336
Cash flows from operating activities	789	1,130
САРЕХ	(383)	(420)
Short-term borrowings	(405)	(747)
Long-term borrowings	570	812
Cash Dividends	(228)	(219)
Others	(100)	245
Cash and cash equivalents at end of period	3,950	3,137

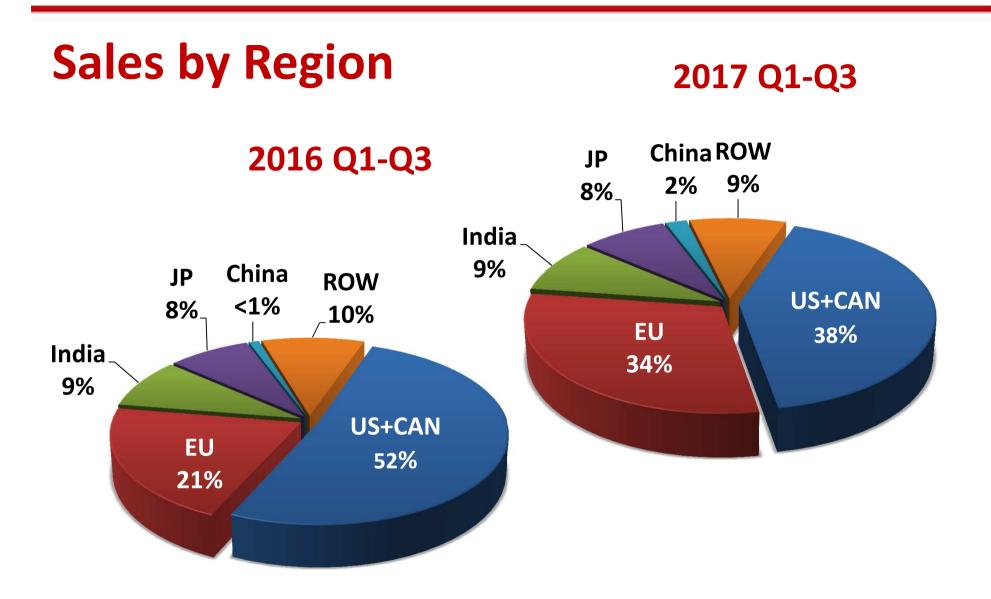














# Trends in US Generic Pharma

### **Trends in US Generic Pharma**

- More Consolidation
- More Competition & Price Erosion on Commodity Generics
- More Focus on Complex Generics
- More Focus on New Therapeutics Agents via 505(b)2

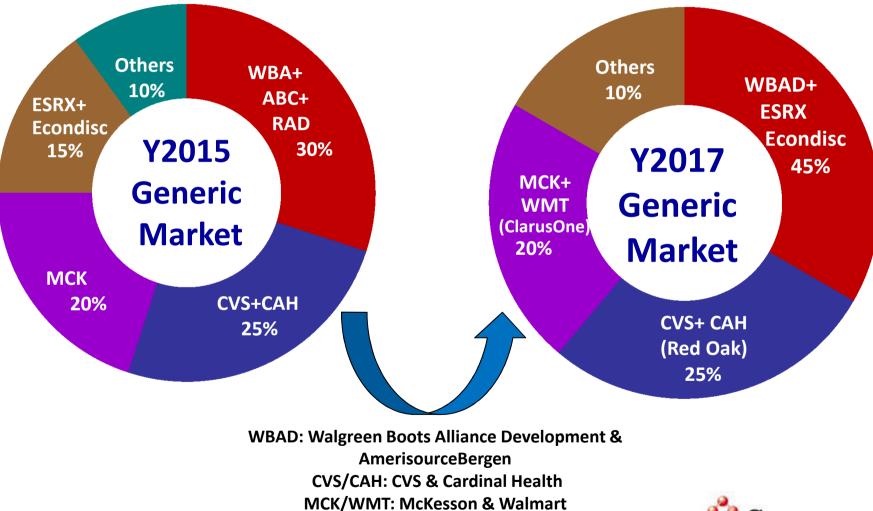


#### **More Consolidation**





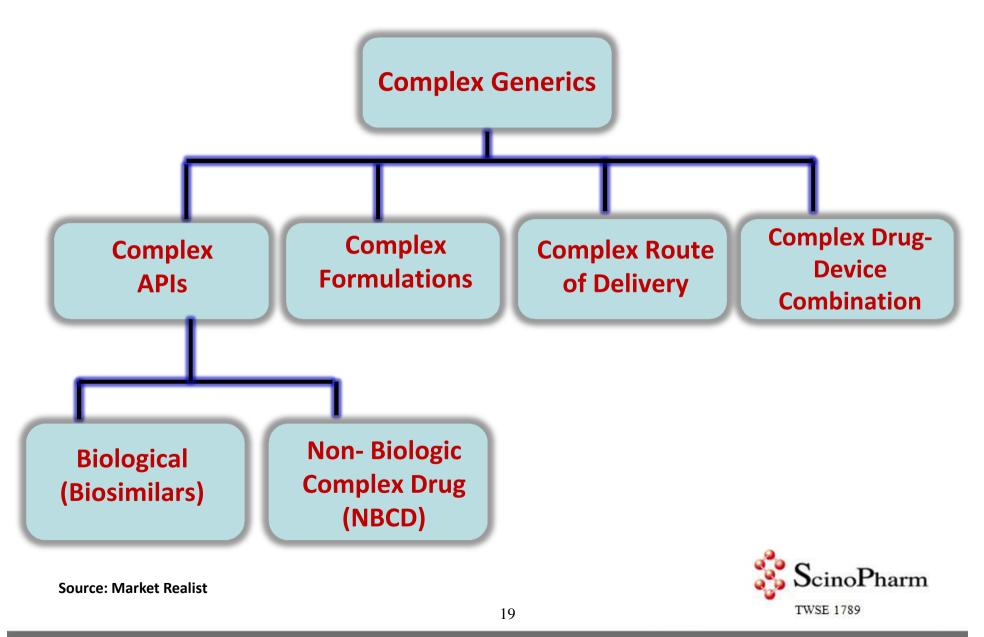
#### **Consolidation of US Drug Buyers**



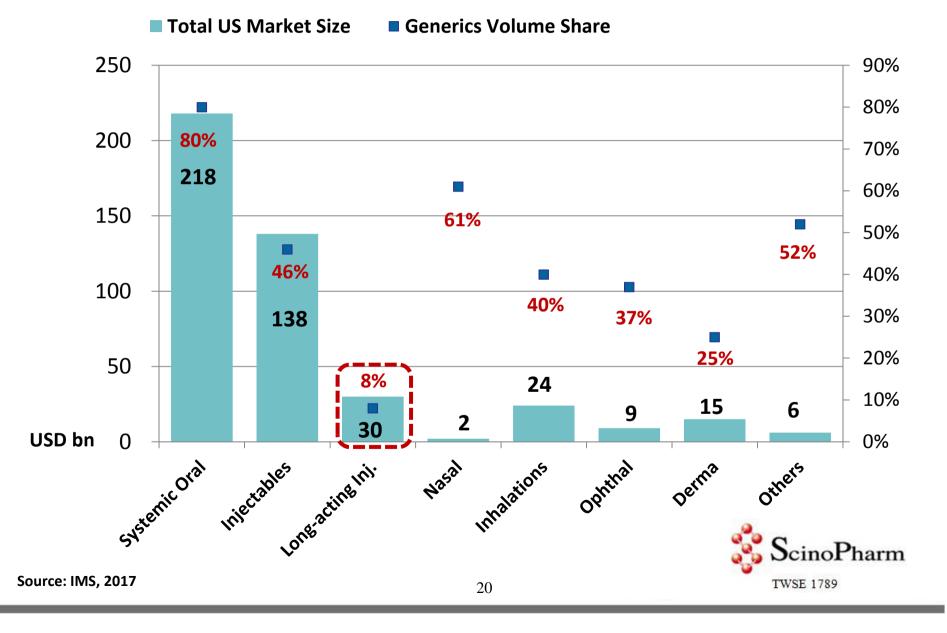
Source: Morgan Stanley Research



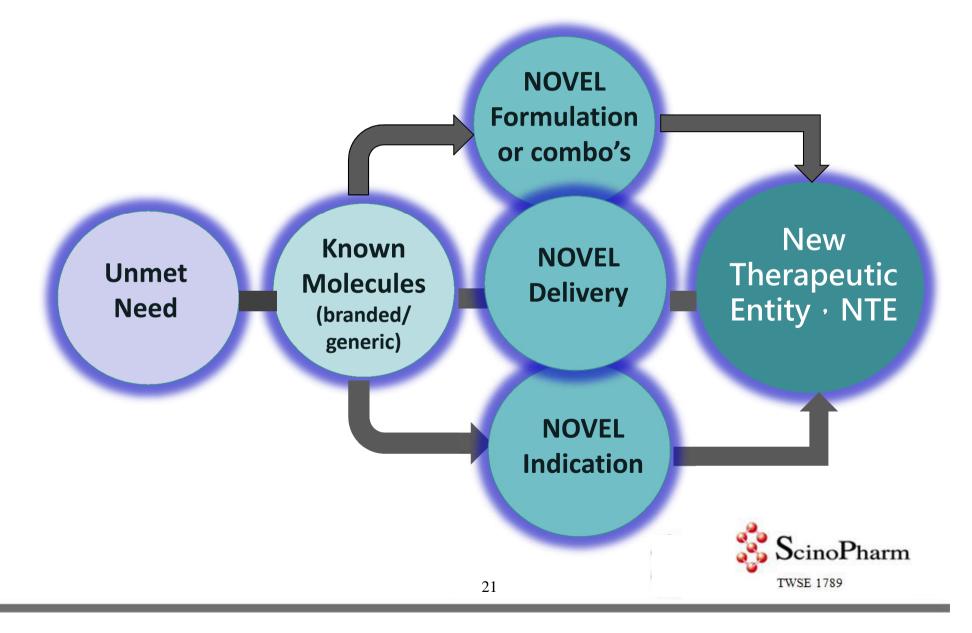
## **Classification of Complex Generics**



#### **Complex Generic Opportunity**



#### **New Therapeutics Agents via 505(b)2**



#### **NTEs- Shorter Timeline & Lower Cost**

#### NCE(New Chemical Entity) process= 10-15 years, USD1-2B



#### NTE(New Therapeutic Entity) process= 3-6 years, USD10-50M

- 505(b)2 pathway in US
- Referencing safety & efficacy data of original molecule



# **ScinoPharm Opportunities**

#### Partnership with marketers in different territories

- Baxter and others
- China Collaboration for US & China dual submissions
- Build a Portfolio of Injectable ANDAs

- Internal development and/or external collaboration; 2ANDAs submitted Acquiring injectable ANDAs

#### Focus on Complex Generics

- Complex API, oncology injectable & combination product
- Long-acting injectables

#### Focus on New Therapeutic Agents (NTE) via 505(b)2



## **2017 Product Launch Plan**

	Туре	Product	Region	Indication	Brand Marketer	Regional Sales	WW Sales
1	Generic API	Desmopressin Acetate	USA	Polyuria	Ferring	US\$166M	US\$405M
	Generic API	Tamsulosin HCl	USA	Benign Prostatic Hyperplasia (BPH)	Boehringer Ingelheim	US\$333M	US\$1706M
<	New Drug API	Oncology Product	US	Non-Small Cell Lung Cancer	N/A	N/A	N/A
	New Drug API	Baxdela™	USA EU	Antibiotics	N/A	N/A	N/A
	Generic Drug	Oncology Injectable	US	Myeloid Leukemia	MDS	US\$183M	US\$278M
-						0	

Source: IMS Data (2015Q3-2016Q2)



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#### Brand Quality with Asian Advantages www.scinopharm.com

