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# ScinoPharm

April 01, 2019



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# **Overview**



### ScinoPharm at a Glance

- Est. in 1997 and HQ in Taiwan (Tainan) with cGMP plants/R&D in Taiwan and China (Changshu) and marketing forces in Taiwan and China (Shanghai)
- Specializing in high potency (steroid/cytotoxic) APIs and injectable formulation, serving customers worldwide
- 70 generic APIs in portfolio with 29 APIs approved \*
  - ■60 active US DMFs (812 DMFs WW) with 31 of them oncology APIs
- 100+ contract projects with 6 launched (4 NCEs) and 8 in phase 3 for NDA filing in 1-3 years \*
- Certified by key international regulators US FDA, EMA, EDQM, Australian TGA, Japanese PMDA, Korea KFDA, Mexico COFEPRIS and German Authority



<sup>\*</sup> As of 2019/03/31

## **Key Updates**

- 2018 consolidated sales were TWD 3.5 billion, up 0.2% yoy, with NPAT of TWD 443 million, up 4.9% yoy. EPS was TWD 0.56
- Team Strengthening
  - Taiwan: CEO, ADM, R&D, QM and FIN
  - China: GM and R&D
- Injectables Progress
  - 2 US ANDA approvals (Decitabine) in Mar 2018 and (Fondaparinux Sodium) in Nov 2018; 1 US ANDA submission in Sep 2018 under FDA review
- Inspection Result
  - Changshu site successfully passed Japan PMDA inspection in May 2018





# **Business Strategies**

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**Optimize Existing Generic API Portfolio** 

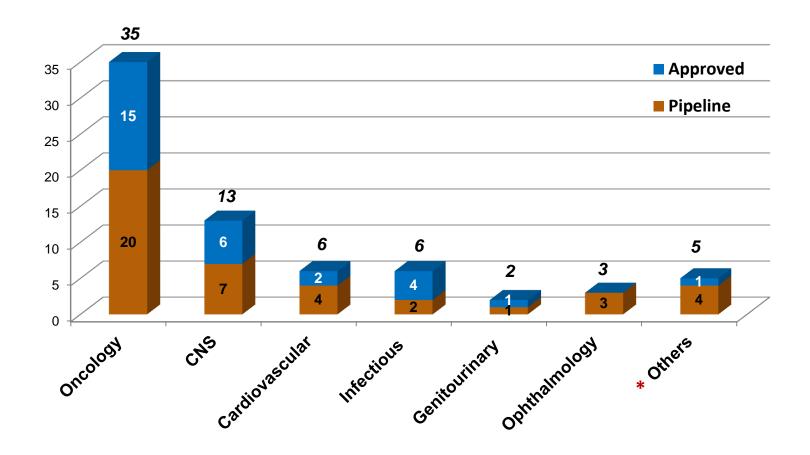
Value up into Injectables

**Expand CDMO Business** 

**Actively Develop Japan and Emerging Markets** 



### **Strategy - Optimize Existing Generics API Portfolio**



<sup>\*</sup> Others include Women's Health, Respiratory, Gastrointestinal, Immunology and Metabolic Data as of 2019/03/31



# Value Up





Oral Solids Immediate Release



Oral Solids Extended Release



Dermatological Semi-Solids



**Sterile Injectables** 



**Otics & Opthalmics** 



**Peptides** 



**Auto Injectors** 



**Respiratory Devices** 

Higher sustainable value through greater entry barriers, and more tech, IP and regulatory requirements



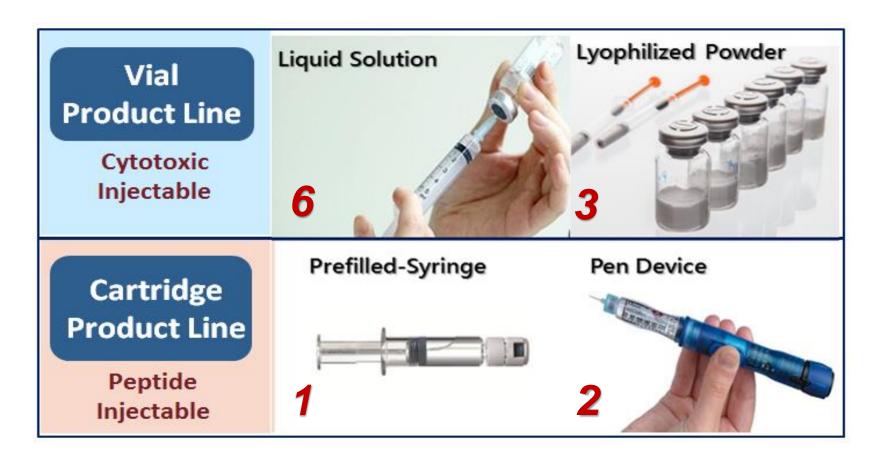
# **Strategy - Value Up into Injectables**

- Leverage leading position in oncology APIs to expand formulation portfolio
- Target complex products with high entry barriers
- ANDA/Dossier development:
  - Apply ANDAs with in-house APIs
  - 3 US ANDA filings (via Injectable CMO) with 2 approvals (Decitabine and Fondaparinux Sodium) \*
  - Submission of 1st ANDA using in house facility in late 2019
- 15 projects with multiple partners in China and US/EU \*
- Offer CMO services for proprietary and generic drugs



<sup>\*</sup> As of 2019/03/31

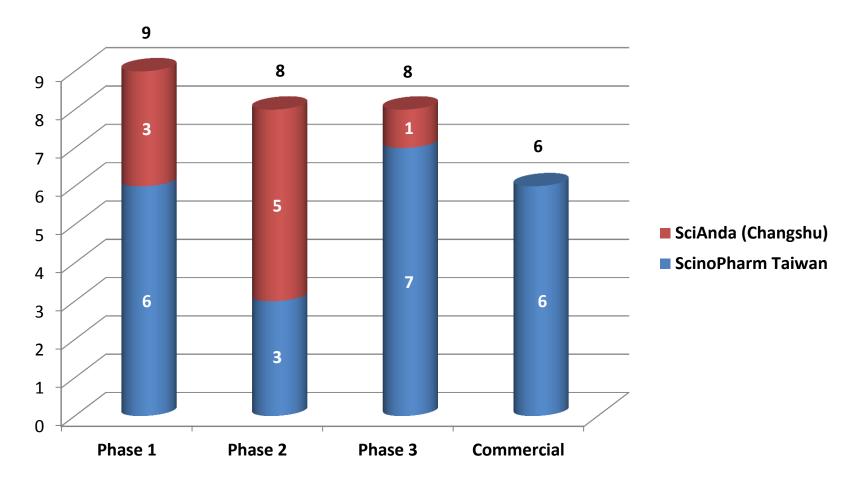
# **In-House Injectables Portfolio**



Data as of 2019/03/31



# **Strategy - Expand CDMO Business**



Data as of 2019/03/31



### **Strategy - Develop Japan and Emerging Markets**

#### **Japan**

- 20 generic customers with 7 from top 10 drug firms
- Direct business with local generic customers
- Support Japanese and foreign pharmaceutical companies for market expansion
- Develop CRAM projects and leverage new injectable capabilities

#### China

- **■** Focus on mid- to late-phase CRO projects
- Seek generic APIs/intermediates with large demand

#### **South America & Russia**

Focus on market development





# **2019 Product Approval Plan**

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Туре	Product	Region	Indication	Brand Marketer	
Generic API	Bivalirudin	CN	Anticoagulant	The Medicines Company	
Generic API	Docetaxel Trihydrate	US	Various cancers	Sanofi	
Generic API	Fulvestrant	US	Breast cancer	AstraZeneca	
Generic API	Tamsulosin	US	Benign prostatic hyperplasia (BPH)	Boehringer Ingelheim	
Generic API	Flumazenil	JP	Benzodiazepine antagonist	Genentech	
Generic Drug		US	Antiemetic agent	Merck	
New Drug	Intermediate for CRAM project	US, EU	Metabolic	CRAM Customer	

Source: IQVIA Data (2017Q4-2018Q3)



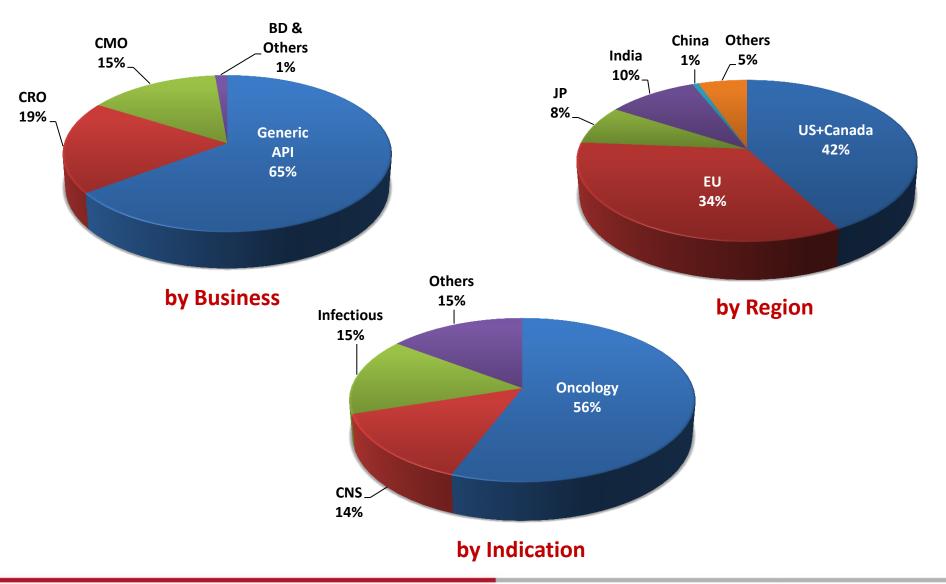


# **Operating Results**

## **Consolidated Income Statement**

In TWD Million, except for EPS	2018 (Audited)		YoY	2017 (Audited)	
Revenue	3,524	100%	0.2%	3,516	100%
Gross Profit	1,543	44%	-0.5%	1,550	44%
<b>Operating Profit</b>	558	16%	-0.1%	559	16%
Income before Tax	491	14%	3.2%	475	14%
Net Income	443	13%	4.9%	422	12%
EPS (NT\$)	0.56	-	-	0.53	-

## **2018 Sales Distribution**





### **Sales Distribution - YoY**

#### By Business Unit: USD

	Generic API	CRO	СМО	BD & Others
2018 Sales	75.8M	22.4M*	17.2M*	1.6M
YoY	-5.6%	64.7%	10.4%	-75.4%

#### **By Indication**

	Oncology	Infectious	CNS	Others
<b>2018 Sales</b>	65.3M	17.9M	16.6M	17.2M
YoY	-14.2%	26.7%	44.3%	21.2%

#### **By Region**

	US & Canada	EU	India	Japan	China	Others
2018 Sales	49.2M	40.1M	11.6M	9.1M	0.8M	6.2M
YoY	4.0%	18.4%	-9.8%	-9.9%	-76.3%	-26.8%

<sup>\*</sup> Sales adjustment due to product reclassification between CRO & CMO

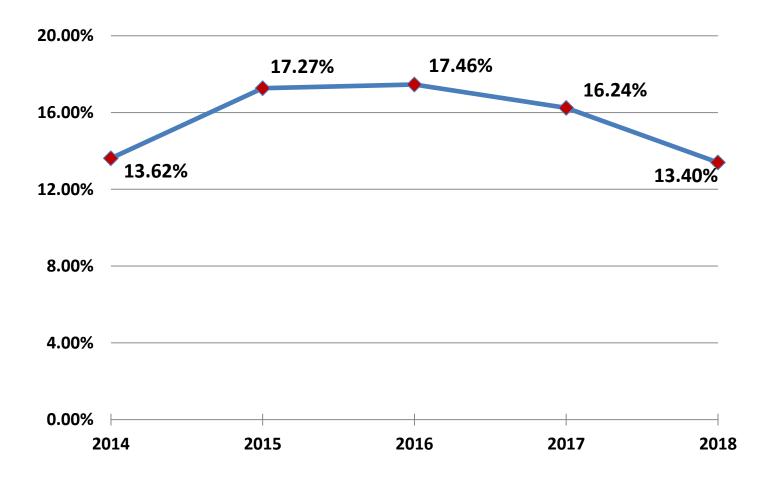


## **Consolidated Balance Sheet**

In TWD Million	2018 (Audited)		2017 (Audited)	
Cash and Cash Equivalents	4,203	34%	3,911	31%
Accounts Receivable	559	4%	567	4%
Inventories	1,364	11%	1,675	13%
Property, Plant & Equipment	4,759	38%	5,089	40%
Other Current/Non-Current Assets	1,678	13%	1,459	12%
Total Assets	12,563	100%	12,701	100%
Financial Debt	1,412	11%	1,692	13%
Other Current Liabilities	534	4%	521	4%
Other Non-Current Liabilities	78	1%	71	1%
Total Liabilities	2,024	16%	2,284	18%
Total Shareholders' Equities	10,539	84%	10,417	82%



## **Financial Debt - to - Equity Ratio**



Financial Debt - to - Equity Ratio = Total Financial Debt / Total Equity



### **Consolidated Cash Flow Statement**

In TWD million	2018 (Audited)	2017 (Audited)	
From Operating Activities	1,231	972	
From Investing Activities	(300)	(437)	
Financial asset measured at amortized cost	(179)	0	
Capital expenditure	(123)	(402)	
From Financing Activities	(627)	(314)	
Effect of foreign exchange rate changes	(12)	(17)	
Net Change in Cash	292	204	
Beginning Balance	3,911	3,707	
Ending Balance	4,203	3,911	





# Q & A





## **Brand Quality with Asian Advantages**

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