

# Second Quarter 2016 On-Line Investor Meeting

August 5, 2016



---

# Disclaimer

This material has been prepared by ScinoPharm Taiwan, Ltd. (“ScinoPharm”).

Any opinions expressed in this material are subject to change without notice as a result of using different assumptions. ScinoPharm is under no obligation to update or keep current the information contained herein.

The **information contained** in this presentation is ScinoPharm’s **confidential** information. Any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it is prohibited and may be unlawful.

**No representation or warranty**, express or implied, is or **will be made** in or in relation to, and no responsibility or liability is or will be accepted by the Company **as to**, the **accuracy or completeness** of this material and any liability therefore is hereby expressly disclaimed.

Statements made in this presentation include forward-looking statements, which include, without limitation, statements about the issues, plans and expectations of ScinoPharm. Without limiting the foregoing, statements including the words “believes”, “anticipates”, “plans”, “expects” and similar expressions are also forward-looking statements. Forward-looking statements reflect, among other things, management’s plans and objectives for future operations, current views with respect to future events and future economic performances and projections of various financial items. **These forward-looking statements involve known and unknown risks**, uncertainties and other factors **which may cause actual results to differ materially from those implied** by such forward-looking statements.

---

# Table of Content

- Overview of ScinoPharm
- Financial & Operating Results in Q2, 2016
- Business Updates



# **Overview of ScinoPharm**

---

# Business Overview

- Company specializes in high potency (steroid/cytotoxic) APIs and is expanding into sterile/aseptic injectable formulations
- Facility & organization built in Taiwan and expanding in China with a new GMP plant in Changshu & marketing base in Shanghai
- 70 generic APIs in current portfolio with 25 APIs launched; 50 US DMFs filed (737 DMFs WW), 30 US DMFs in oncological APIs. 100+ NCE CRAM projects, with 5 APIs launched and 5 in phase III for NDA filing in 2-3 years
- Fully compliant with world-class cGMPs and international regulatory requirements; Certified by US FDA, EMA, Australian TGA, Japanese PMDA, etc.

# World Class API Facilities

## Taiwan

- 6.6 hectares of land, 330K sqft facilities with >200M<sup>3</sup> reactor volume
- 5 of 16 production lines equipped with high potency capabilities for cytotoxic/steroids
- Passed US FDA, EMA, Australian TGA, Japanese PMDA inspections & 300+ cGMP customer audits
- Provides comprehensive contract research & manufacturing services for Brand drug companies
- Global Market served

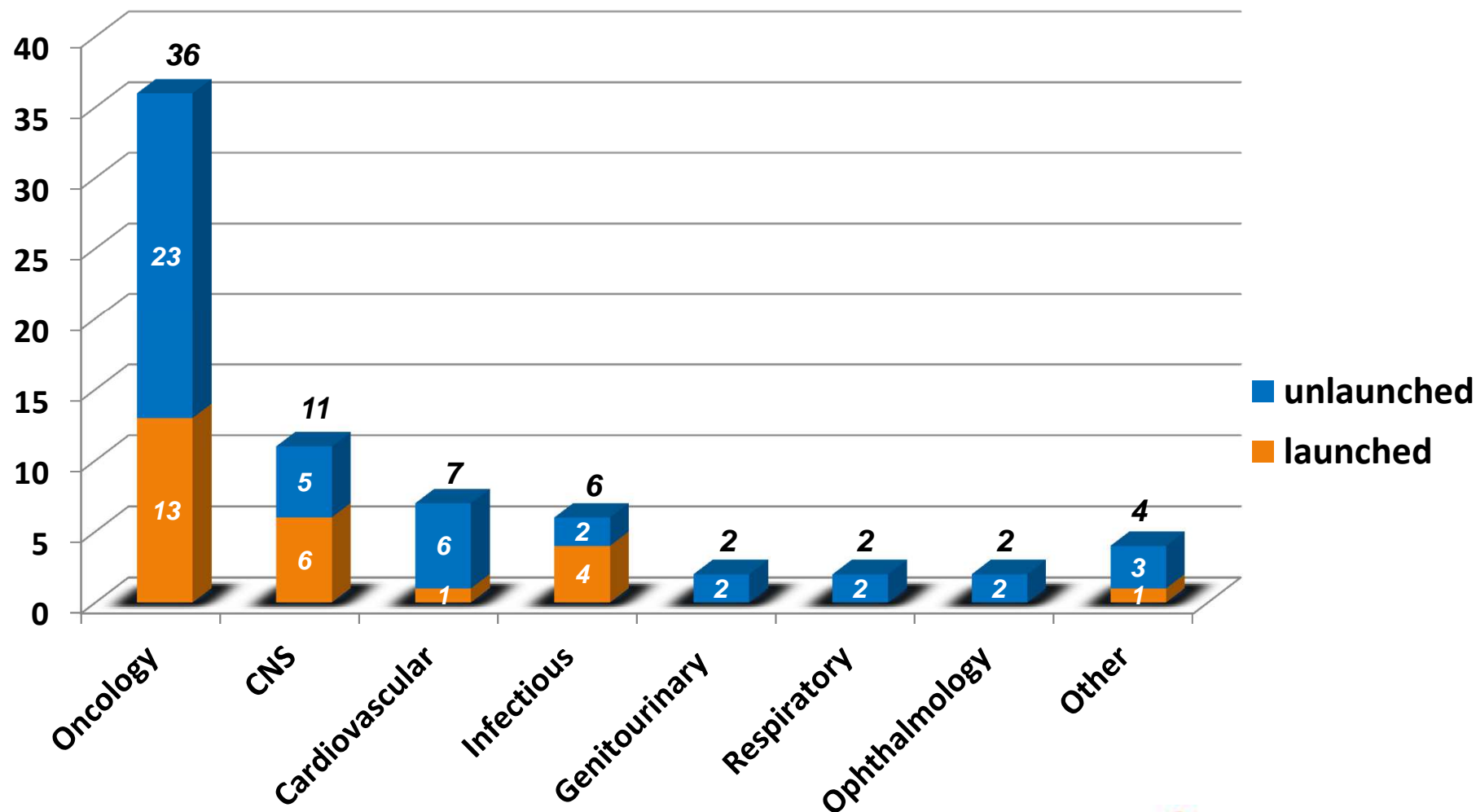


## China

- 6.5 hectares of land with > 250M<sup>3</sup> reactor volume
- 3 of 7 production lines equipped with high potency capabilities for cytotoxics
- US FDA approved cGMP facility for intermediates & high potency APIs
- Full scope capabilities in developing and producing APIs from small to large scale for generic & CRAM markets
- Global market served including China

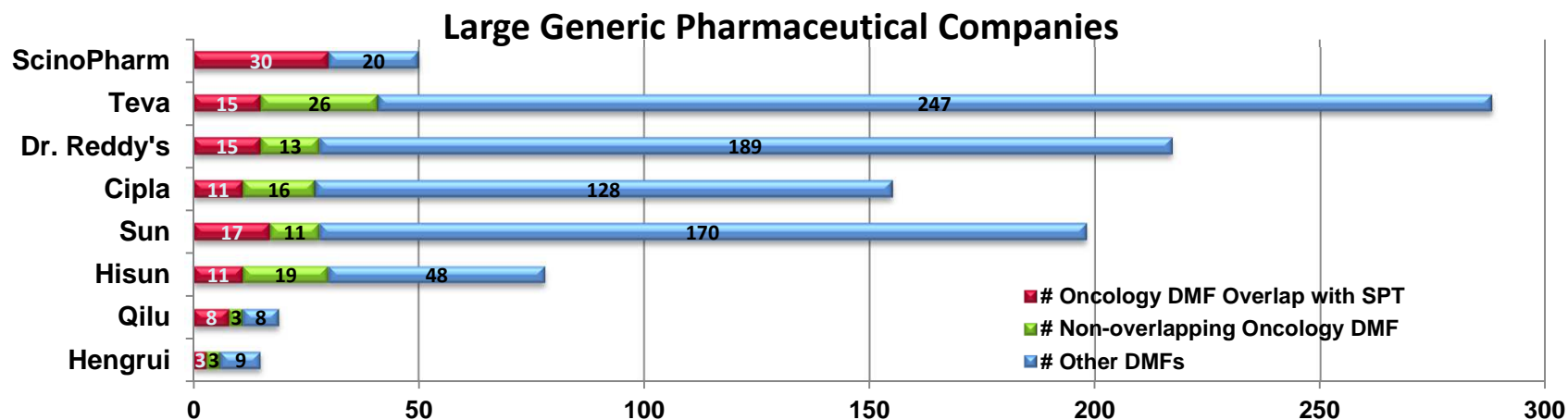
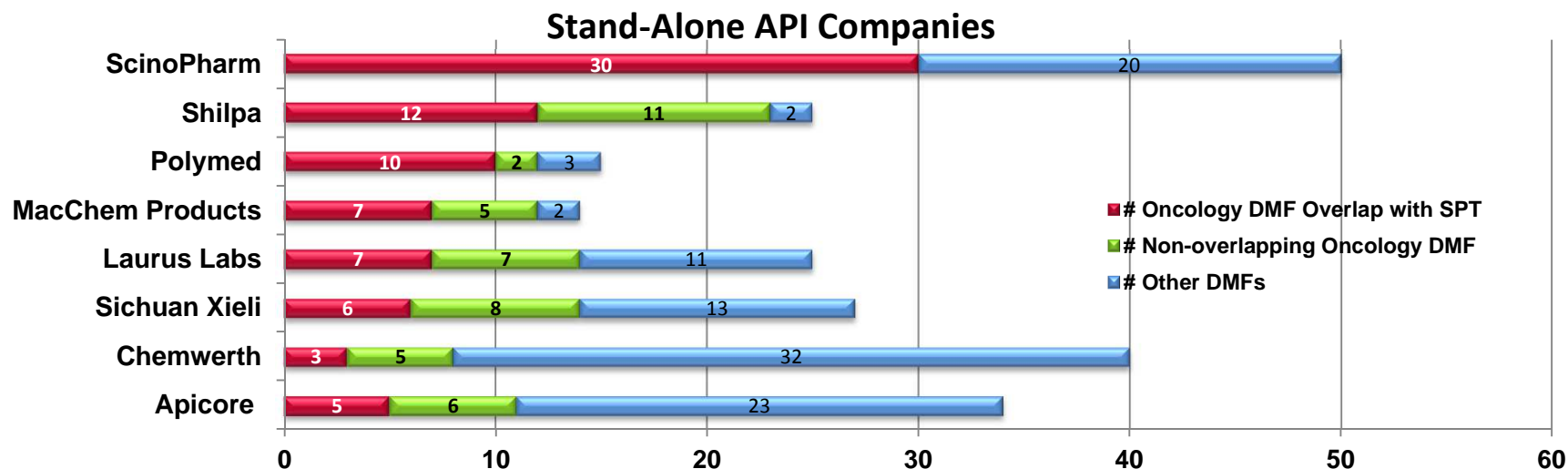


# Strong Generics Product Portfolio



Note: Other (Women's Health, Gastrointestinal, Immunology and Metabolic)

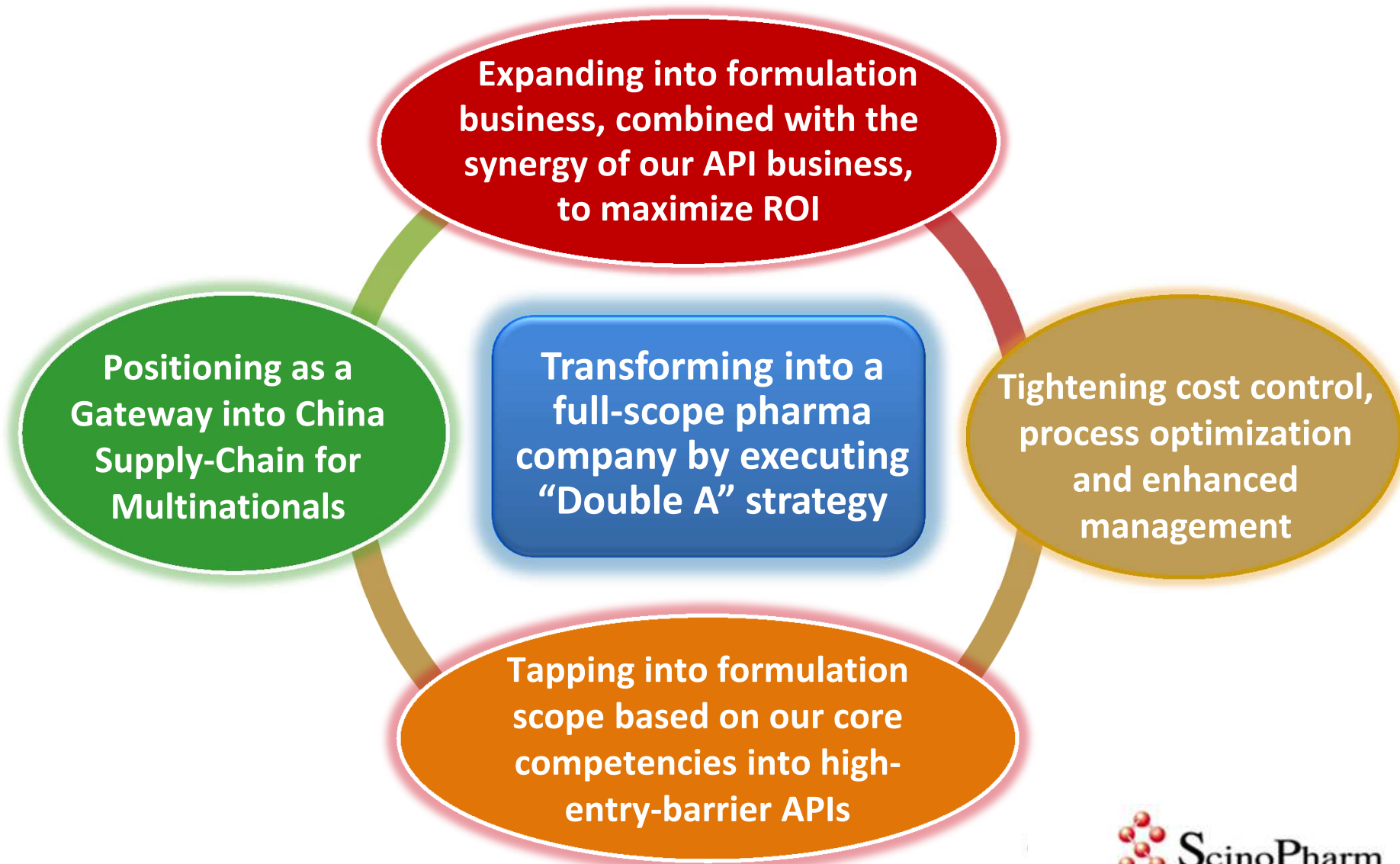
# ScinoPharm - Oncology API Leader



Source: US FDA DMF Q1 2016 database



# We are Transforming our Company



# Keys to Generic Formulation Business

Opportunity	Strategy	Tactics
<ul style="list-style-type: none"><li>✓ Already the leader in providing oncological APIs to regulated markets worldwide</li><li>✓ Injectable CMOs are in undersupply condition</li><li>✓ Can be customer's injectables provider by developing formulations using our own oncological APIs or others' APIs, up to and including filing for ANDA with FDA</li></ul>	<ul style="list-style-type: none"><li>✓ Developing dossiers per our difficult-to-make APIs to increase value proposition in the supply chain</li><li>✓ Targeted delivery &amp; extended release of proven APIs via 505(b)2 fast track</li><li>✓ Collaborating with start-ups &amp; research institutes, focusing on un-met oncology medical needs of high prevalence in Asia</li></ul>	<ul style="list-style-type: none"><li>✓ Expanding formulation portfolio</li><li>✓ Building on-site oncology injectable facility and establishing an integrated supply chain</li><li>✓ promoting our formulations via strategic alliances, especially in China and US/EU</li></ul>

Results

- 2 US ANDAs
- 11 co-developing and cost/profit sharing products with various partners

# Strategic Alliance Highlights

\* Already launched

Partner	Product	Indications	Region	Launch Year(E)	Remarks
Genovate	Entecavir	Hepatitis B Viral	Taiwan	2013*	1 <sup>st</sup> co-developed formulation product launch
Sagent	Oncology Injectable	Myeloid Leukemia	US	2017	1 <sup>st</sup> US ANDA filing, triggered US FDA inspection in Changshu site
Foresee	Leuprolide	Prostate cancer	US	2018	505(b)2 NDA CRAM + Equity
Coland	Bortezomib	Multiple Myeloma	China	2020	1 <sup>st</sup> co-developed drug in China to trigger CFDA inspection in Changshu site
	Azacitidine	MDS	China	2021	Co-developed formulation in China
Lee's Pharma	Fondaparinux	Anti-thrombotic	China	2021	Co-development collaboration
	Travoprost Bimatoprost	Glaucoma	China	2020	
Nanjing King Friend	Regadenoson	Stress agent for heart scan	China	2020	Co-developed formulation in China
US partner	Project A	non-small cell lung cancer	US	2020	US NDA 505(b)2 with Paragraph IV filing / The estimated launch year is subject to litigation results
US & China partners	Project B	imaging agent	US	2020	ANDA with Paragraph IV filing / The estimated launch year is subject to litigation results

---


# First New Drug Collaboration Project

- ScinoPharm's first new drug development project collaborates with an external partner, CVie Therapeutics, from a discovery (pre-IND) perspective.
- Both parties aim to identify a new generation compound to Istaroxime, CVie's acute heart failure treatment currently in late Phase IIb trials in Italy and China.
- The primary goal of the new generation compound is to possess oral bioavailability while maintaining Istaroxime's unique dual luso-inotropic function. ScinoPharm will provide medicinal chemistry design and synthesis, and CVie will apply their vast biological know-how to screen and identify the new candidate.

---

# Collaboration For Chronic Heart Failure Therapy

- Istaroxime is a first-in-class luso-inotropic agent under development for the treatment of acute decompensated heart failure. It is an innovative medication for the improvement of both systolic and diastolic heart function.
- The successful new generation compound may be positioned for both acute and chronic heart failure, which is expected to target a larger patient population than acute heart failure alone.
- ScinoPharm aims to be the primary chemistry, manufacturing, and controls (CMC) service provider to furnish material for both clinical and commercial phases.



# **Financial & Operating Results in Q2, 2016**

# Quarterly P&L - Consolidated

In NT\$ million, except for EPS	2Q,'16 (Reviewed)	1Q,'16 (Reviewed)	2Q,'15 (Reviewed)	QoQ	YoY
Operating Revenue	1,015	1,022	963	-1%	5%
Gross Profit	465	431	365	8%	27%
<i>Gross margin</i>	<i>46%</i>	<i>42%</i>	<i>38%</i>		
Operating Expenses	(236)	(236)	(239)	0%	-1%
Operating Income	229	195	126	17%	82%
<i>Operating margin</i>	<i>23%</i>	<i>19%</i>	<i>13%</i>		
Other Rev.(Exp.)	(29)	(4)	106	625%	-127%
Net Income before Tax	200	191	232	5%	-14%
Net Income after Tax	174	172	132	1%	32%
<i>Net margin after tax</i>	<i>17%</i>	<i>17%</i>	<i>14%</i>		
EPS (after tax)	0.24	0.24	0.18	0%	33%

# Half Year P&L - Consolidated

In NT\$ million, except for EPS	1H,'16 (Reviewed)	1H,'15 (Reviewed)	YoY
Operating Revenue	2,037	1,942	5%
Gross Profit	896	709	26%
<i>Gross margin</i>	<i>44%</i>	<i>37%</i>	
Operating Expenses	(471)	(442)	7%
Operating Income	425	267	59%
<i>Operating margin</i>	<i>21%</i>	<i>14%</i>	
Other Rev.(Exp.)	(34)	99	-134%
Net Income before Tax	391	366	7%
Net Income after Tax	346	245	41%
<i>Net margin after tax</i>	<i>17%</i>	<i>13%</i>	
EPS (after tax)	0.47	0.34	38%



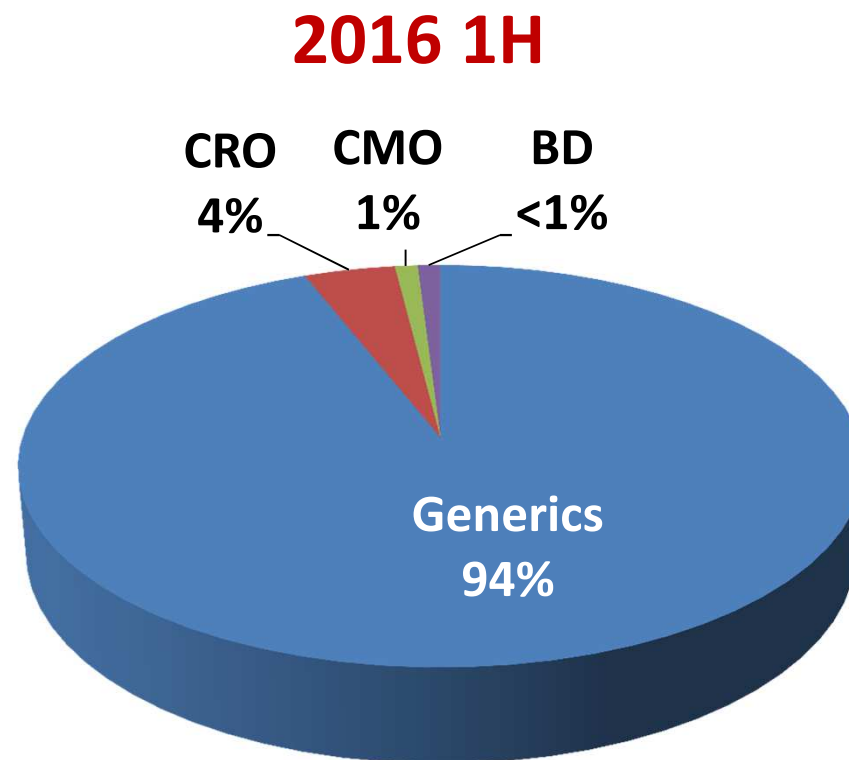
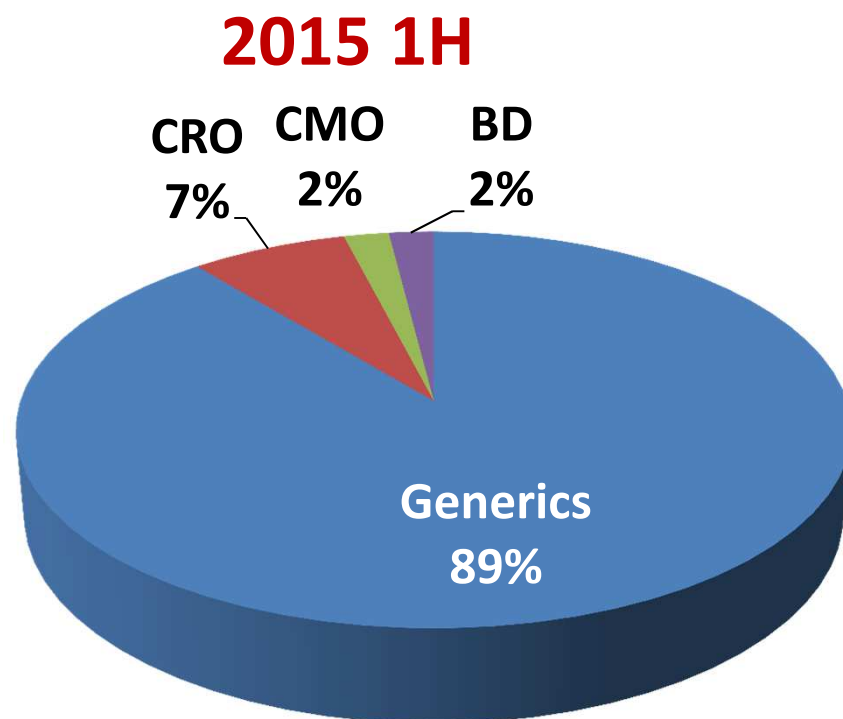
# Balance Sheet - Consolidated

In NT\$ million	2016/6/30 (Reviewed)		2015/6/30 (Reviewed)	
Cash and Cash Equivalents	2,964	24%	2,410	20%
Accounts Receivable	678	5%	568	5%
Inventories	2,062	16%	2,315	19%
Long-Term Investments	364	3%	339	3%
Property, plant & equipment	5,355	43%	5,142	43%
Other assets	1,122	9%	1,100	10%
Total Assets	12,545	100%	11,874	100%
Current Liabilities	2,248	18%	2,333	19%
L-T Liabilities and Others	339	3%	91	1%
Stockholders' Equities	9,958	79%	9,450	80%

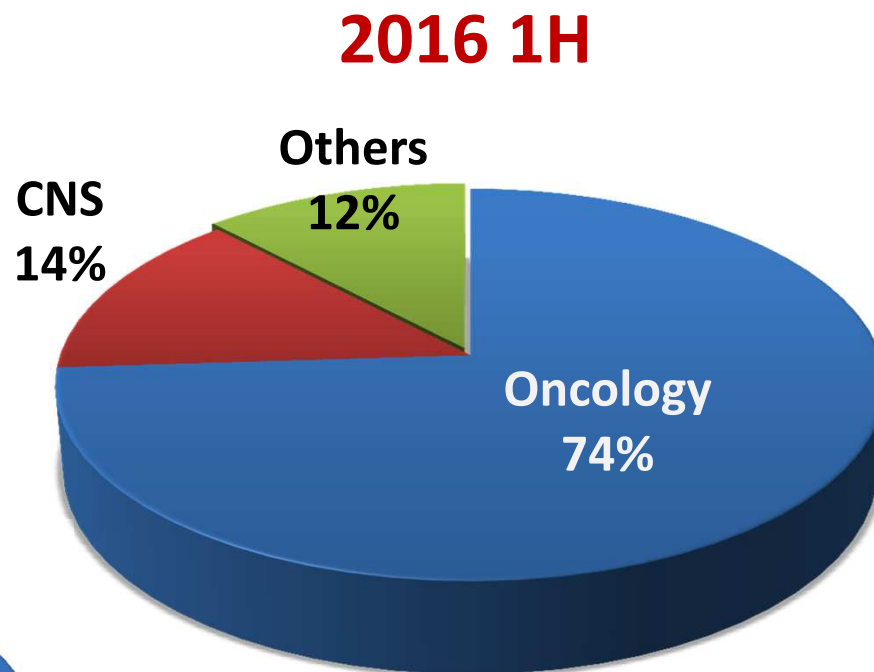
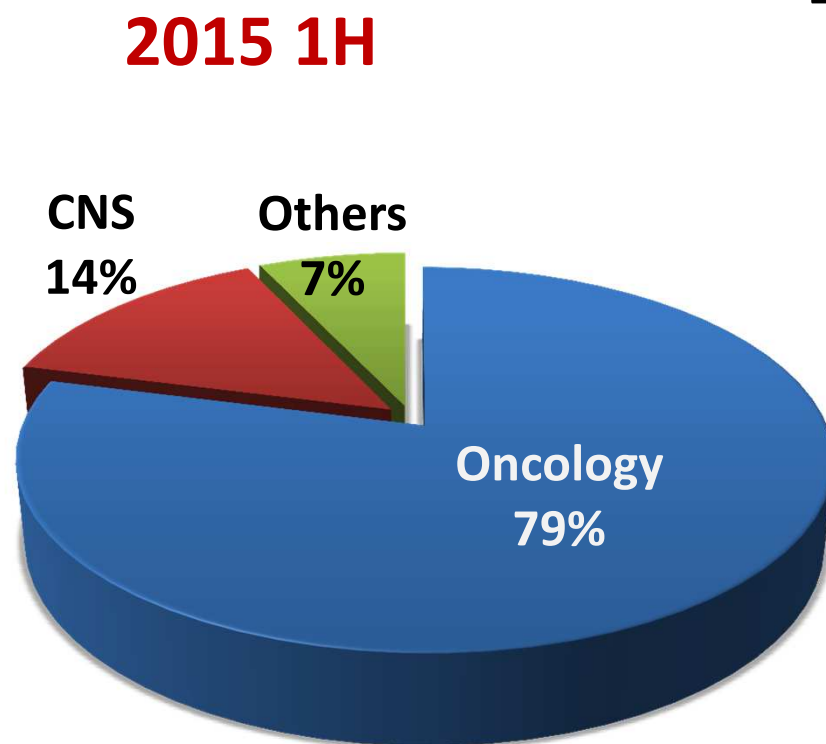
# Cash Flows - Consolidated

In NT\$ million	1H 2016 (Reviewed)	1H 2015 (Reviewed)
Cash and cash equivalents at beginning of period	2,336	1,928
Cash flows from operating activities	826	589
CAPEX	(371)	(345)
Short-term borrowings	(241)	212
Long-term borrowings	255	-
Others	159	26
Cash and cash equivalents at end of period	2,964	2,410

# Sales by Business

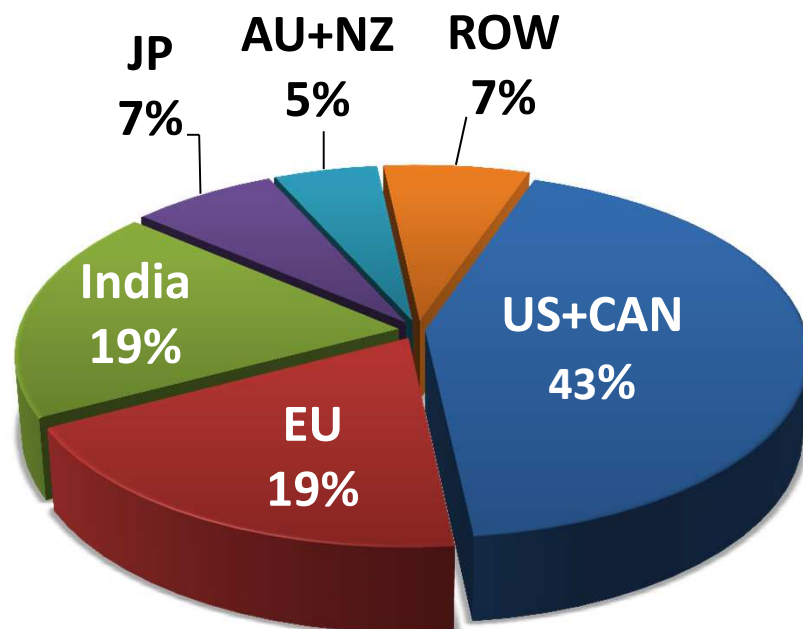


# Sales by Indications

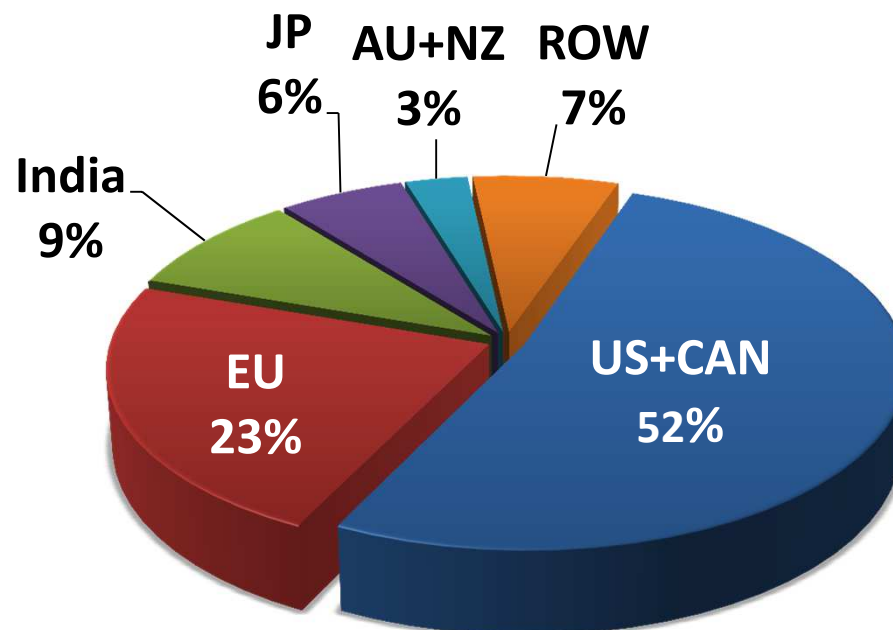


# Sales by Region

**2015 1H**



**2016 1H**



# **Business Updates**

---

# Injectable Plant Progress

- Entire facility includes space for R&D, quality control, washing, sterilization, manufacturing, filling, lyophilization, packaging, and storage
- Granted building use permit at the end of 2015. To complete registration batch production by 2017. Expected to submit the 1st home-made ANDA in 2018 and pass US FDA inspection in 2019
- Target is injectables with high entry barrier/ high unit-priced generics like oncologicals and peptides. Will offer CMO services for brand drugs and self-developed drug
- 10 drugs planned with the indications of cancer, diabetes, osteoporosis, multiple sclerosis and antinauseant

---

# Complies with Latest CGMP Standards





# Research Lab



# Process Area



# Process Area

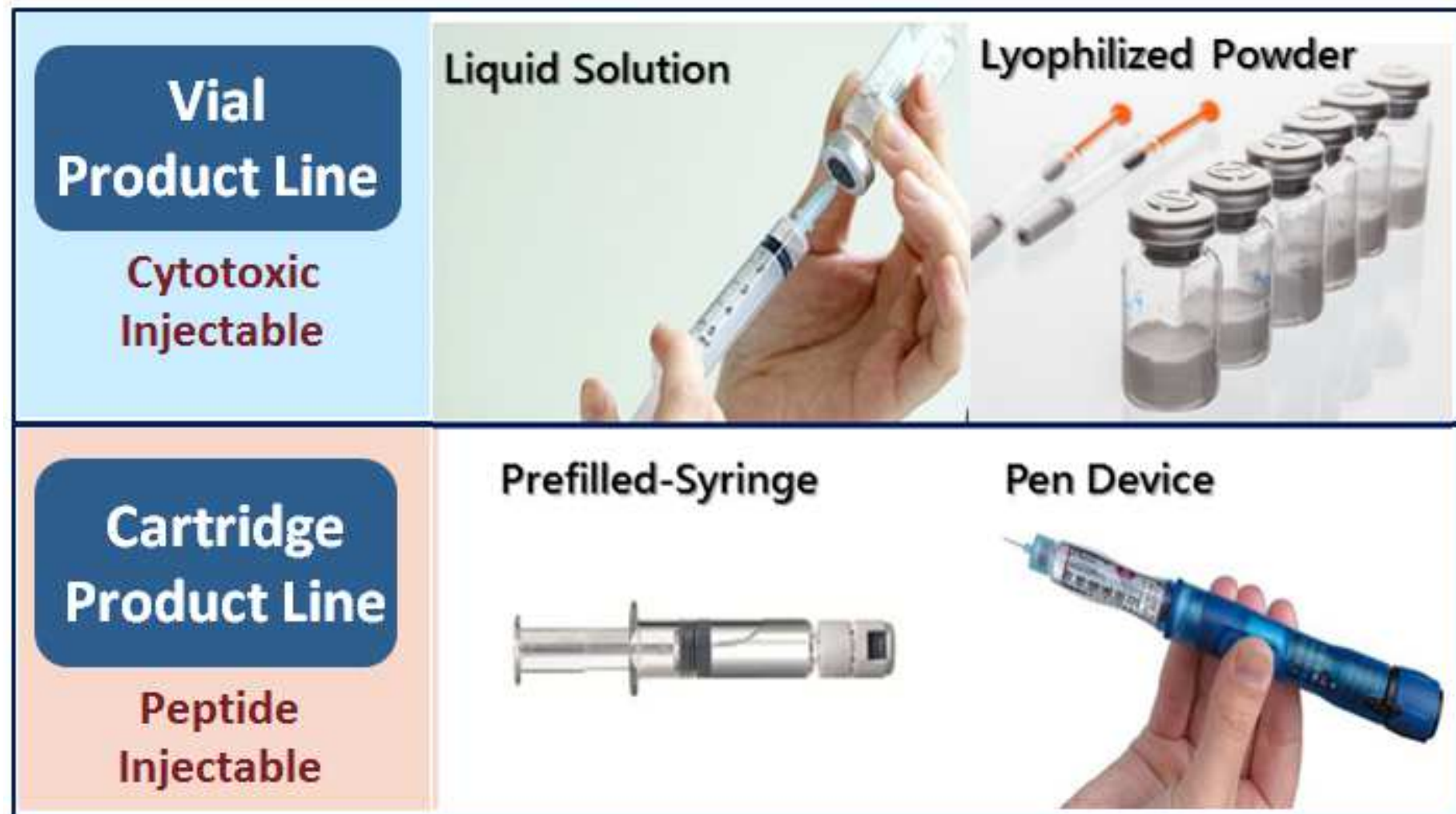




# Utility Area



# Aseptic Fill & Finish Service



# Diversified CRAM Portfolio

Stage	First Launch Year	Indication	Location
Commercial	2005	Eluting Stent	US
Commercial	2009/2013	Skin Infection/HAP	US/EU
Commercial	2011	Depression	US
Commercial	2012	Obesity	US
Commercial	2013	Seizure	US
Stage	Est. NDA Filing Year	Indication	Location
Phase III	2016	Infections	US / EU / Asia
Phase III	2017	Ovarian Cancer	US / EU
Phase III	2017	Prostate Cancer	US
Phase III	2017	Ovarian Cancer	CN
Phase III	2018	Parkinson's Disease	US

# Selected List of CRAM Projects at Changshu

Customer	Project Type	Product Indication/stage	Product Type	Remarks/ Market
Top 10 global pharma	CMO	Approved antidepressant drug in US	GMP Intermediate	Passed Mexican authority (APIF) GMP inspection
Top 5 global pharma	CMO	Approved African sleeping disease drug	API	Site transfer from Taiwan
Lee's Pharma	CRO	+15 items including topical anesthetic, brain tumor, antibiotic, hypertension, eye drop, etc.	API	China
China pharm company	CRO	Phase II/ III clinical trial for cancer	API	China
China pharm company	CRO	Phase IIb for age-related macular degeneration	API	US/China
Taigen Biotech	CRO	Phase II clinical trial for myocardial infarction	API	China/Taiwan
US-based new drug company	CRO	Phase II clinical trial for prevention of HIV infection	API	US
Alsan Pharmaceuticals	CRO	Phase II clinical trial for cancer	API	China/Global
Top 5 global pharma	CRO	Phase II clinical trial for diabetes	Intermediate	US
Top 5 global pharma	CRO	Phase I clinical trial	API	NA
US NASDAQ listed pharma	CRO	Phase III clinical trial for opioid-induced constipation	Crude API	US

# 2016 1H Major Products

- account for 60% of total sales

API	Indications	2015 MKT Share	# of US DMF/EDMF & other Filings
Irinotecan HCl	Antineoplastic	64%	62
Docetaxel Anhydrous	Antineoplastic	33%	68
Paclitaxel	Antineoplastic	31%	57
Exemestane	Antineoplastic	18%	44
Galantamine HBr	Antipsychotic	12%	38
Gemcitabine	Antineoplastic	8%	76

\*Source: IMS data from Newport



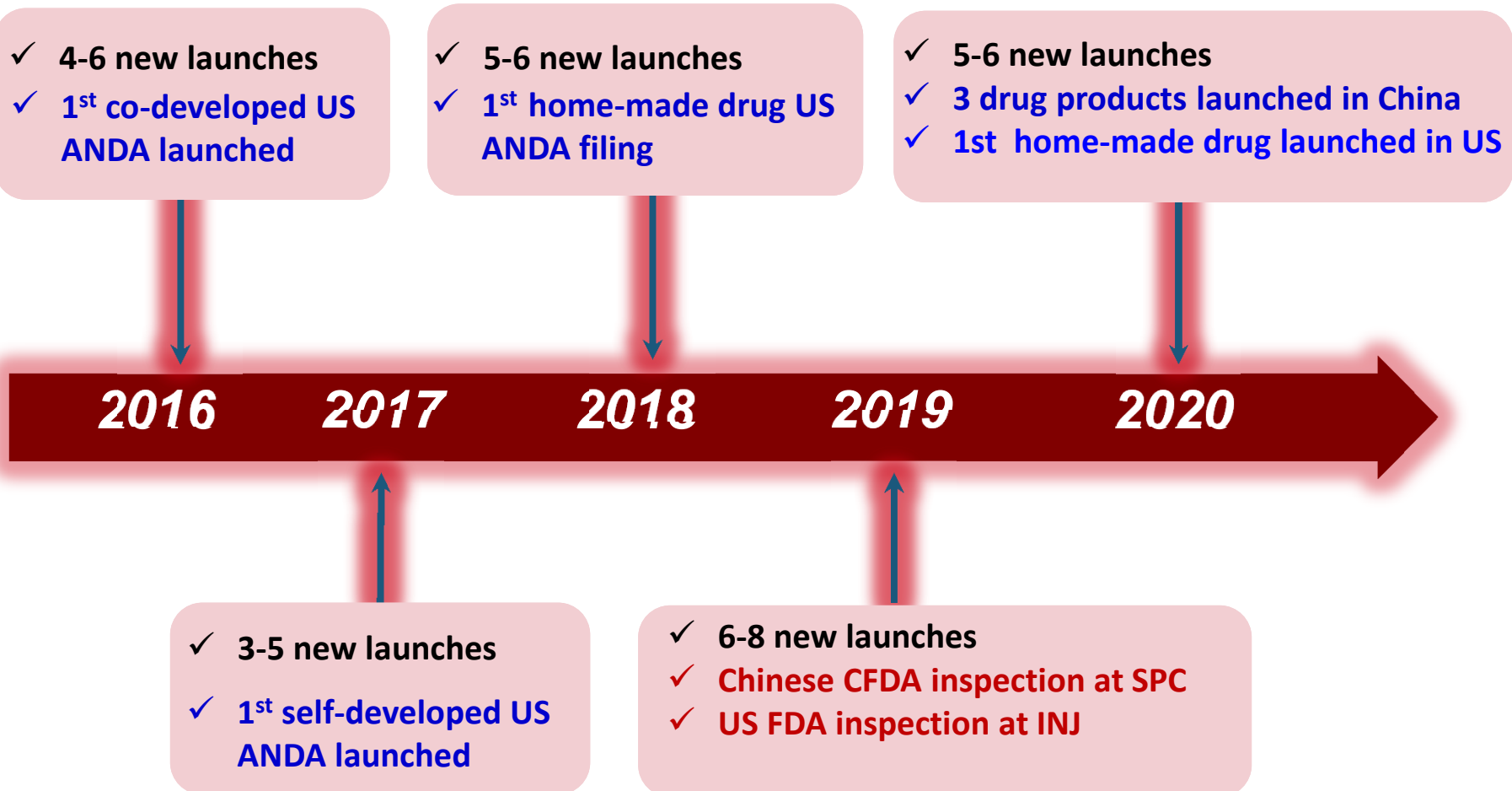
# 2016 API Product Launch Plan

API	Region	Indication	Brand Marketer	Regional Sales	WW Sales
✓ Azacitidine	USA	Myelodysplastic syndromes (MDS)	Celgene	US\$248.1M	US\$751.6M
Desmopressin Acetate	USA	Polyuria	Ferring	US\$150.1M	US\$395.8M
✓ Entecavir	USA Singapore Australia	Hepatitis B Virus (HBV)	Bristol-Myers	US\$262.5M (USA only)	US\$1,576.6M
✓ Flumazenil	Korea	Reversal of the sedative effects of benzodiazepines	Roche	N/A	US\$84.0M
✓ Gemcitabine HCl	Middle East	Pancreas, Lung, Ovary, Breast Cancers.	Eli Lilly	N/A	US\$547.9M
Tamsulosin HCl	USA	Benign Prostatic Hyperplasia (BPH)	Boehringer Ingelheim	US\$410.0M	US\$1,818.4M

Source: IMS Data (2014Q4-2015Q3)

✓ Launched

# Pipeline



---

***Q*uestions**

**&**

***A*nswers**



## Brand Quality with Asian Advantages

[www.scinopharm.com](http://www.scinopharm.com)

