ScinoPharm

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ScinoPharm Management Presentation

2017/11/29

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Table of Content

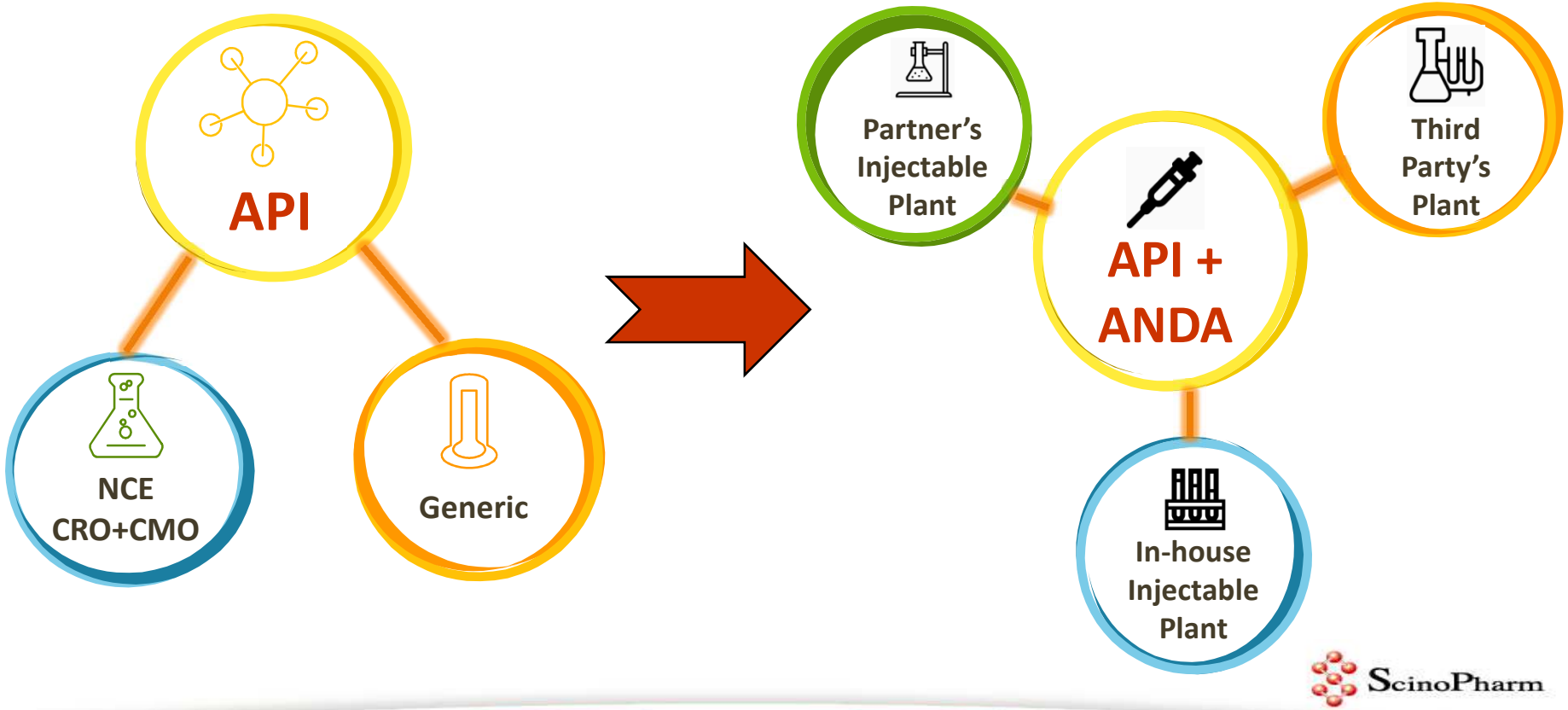
- Overview of ScinoPharm
- ScinoPharm's Strategies and Opportunities
- Operating Results & Business Updates

Overview of ScinoPharm

ScinoPharm at a Glance

- ScinoPharm specializes in high potency (steroid/cytotoxic) APIs provider and injectable formulation developer, serving customers worldwide
- Facility & organization established in Taiwan and expanding in China with a new GMP plant in Changshu & marketing base in Shanghai, China
- 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 3 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, Korea KFDA, Mexico COFEPRIS and German Authority

Specialty Pharmaceutical Company with Two Businesses



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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

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World Class Facilities

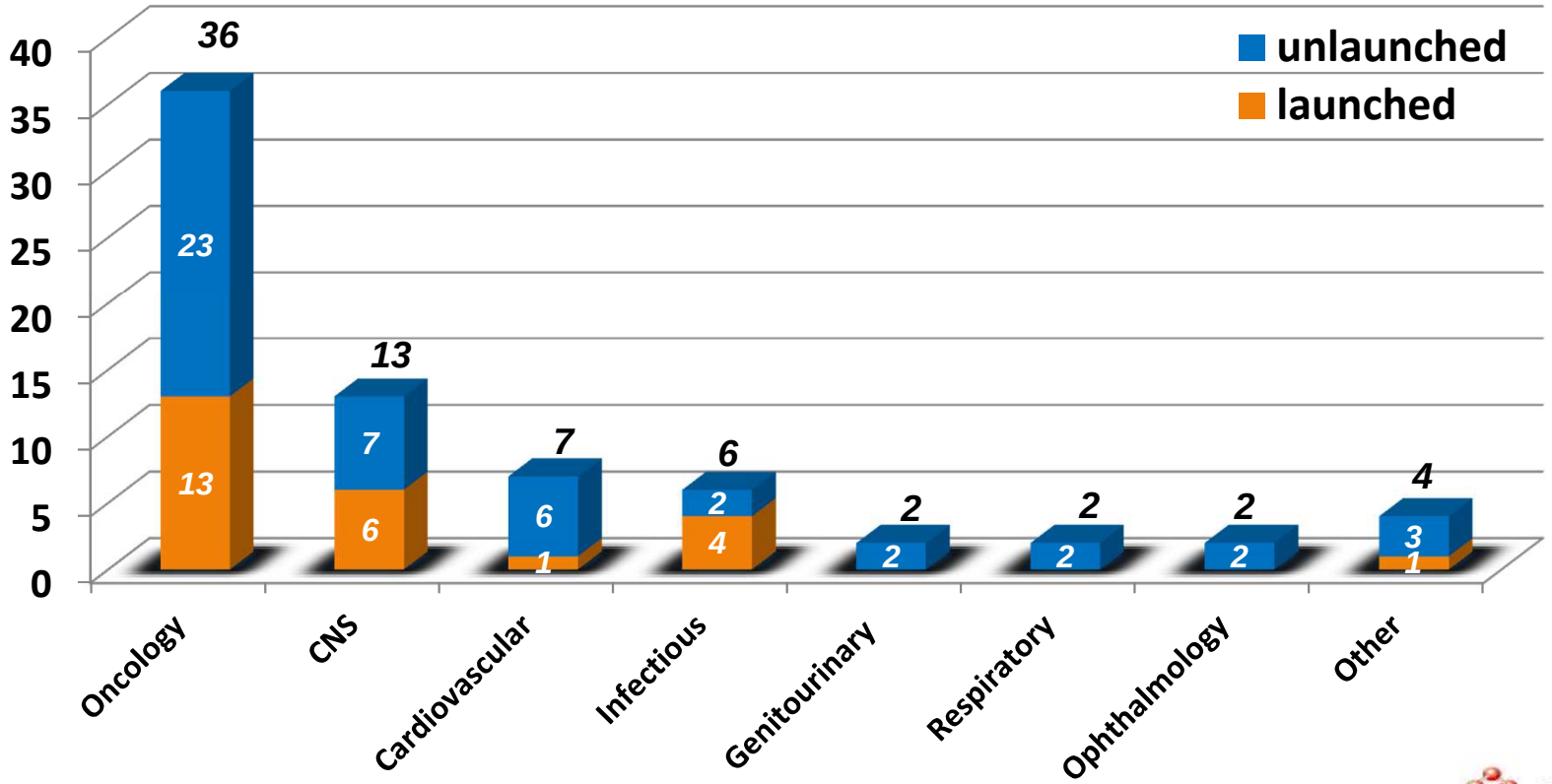
Taiwan

- 6.6 hectares of land, 330K sq.ft. facilities with >200M^3 reactor volume
- 5 of 16 production lines equipped with high potency capabilities for cytotoxic/steroids
- Passed US FDA, EMA, EDQM, Australian TGA, Japanese PMDA inspections, & 300+ cGMP customer audits
- Provides comprehensive contract research & manufacturing services for brand drug companies
- In-house injectable plant with vial and cartridge production lines for oncologicals and peptides

China

- 6.7 hectares of land with > 250M^3 reactor volume
- 3 of 7 production lines equipped with high potency capabilities for cytotoxics
- US FDA approved cGMP facility for intermediates & high potency API
- Full scope capabilities in the development and production of APIs on small to large scales for generic & CRAM markets
- Partnerships with downstream formulation and target for global market including China

Strong Generics Product Portfolio



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

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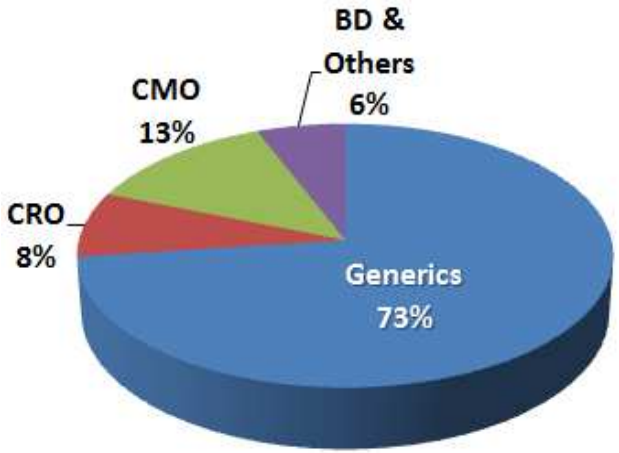
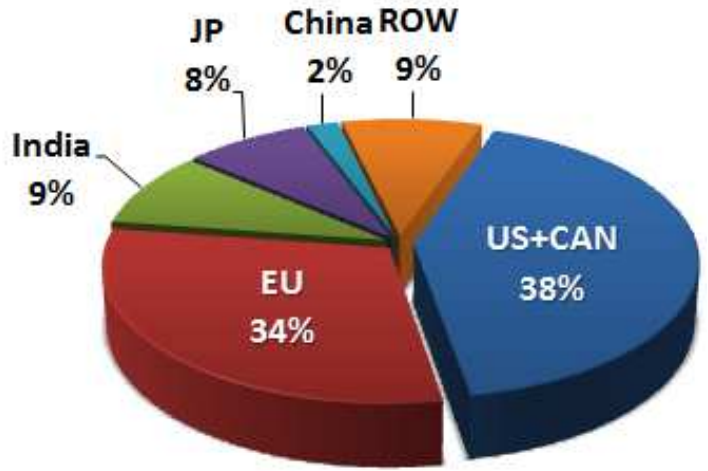
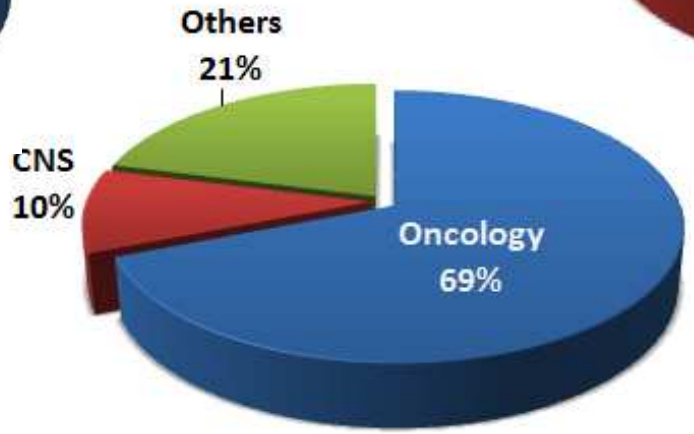
2017 Q1-Q3 Sales Distribution



by Business



by Region



by Indications

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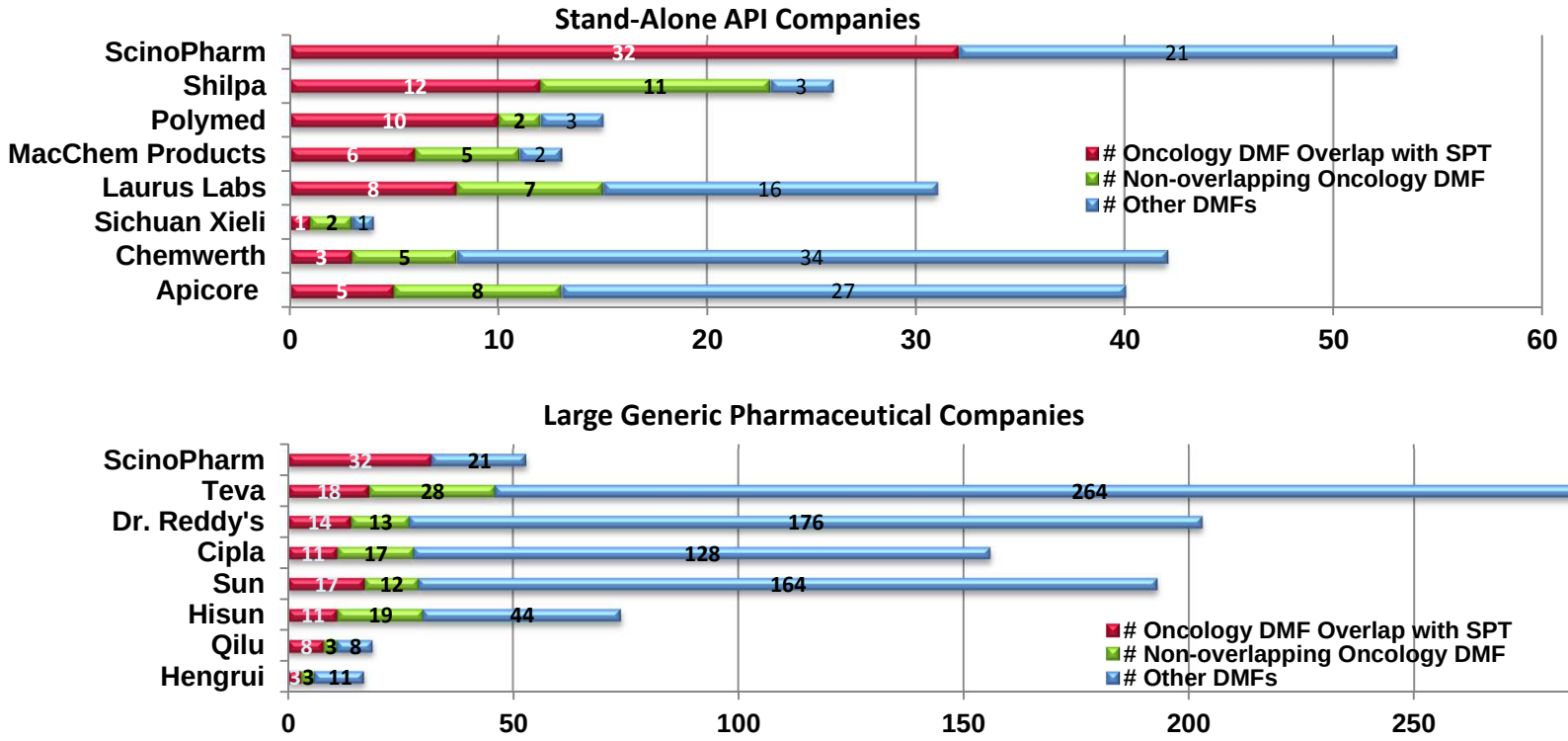
ScinoPharm - Oncology API Leader



Source: US FDA DMF Q2 2017 database

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ScinoPharm's

Strategies and Opportunities

Focused To Achieve Our Goals

1.Deploying the network of development, production and distribution of injectables

- Develop dossiers per our difficult-to-make APIs (complicated synthesis & analytical methods) plus specialized injection devices
- Build partnerships and to achieve critical mass workforce for in-house injectable plant facility

2.CRAM has promising development potential in the next three years

- Focus on small-molecule targeted therapies and CNS agents based on new mode of action
- Provide integrated service from API to formulation for niche injectables

3. Active development of Emerging and Japanese market

- Target projects to utilize capacity and accelerate growth for Changshu site
- Develop partnership with major Japanese pharmaceutical companies and international pharmaceutical groups with Japan-based operation site

4.Continue optimizing existing generic APIs

- Maintain the market share and profit of the top 5 marketed products

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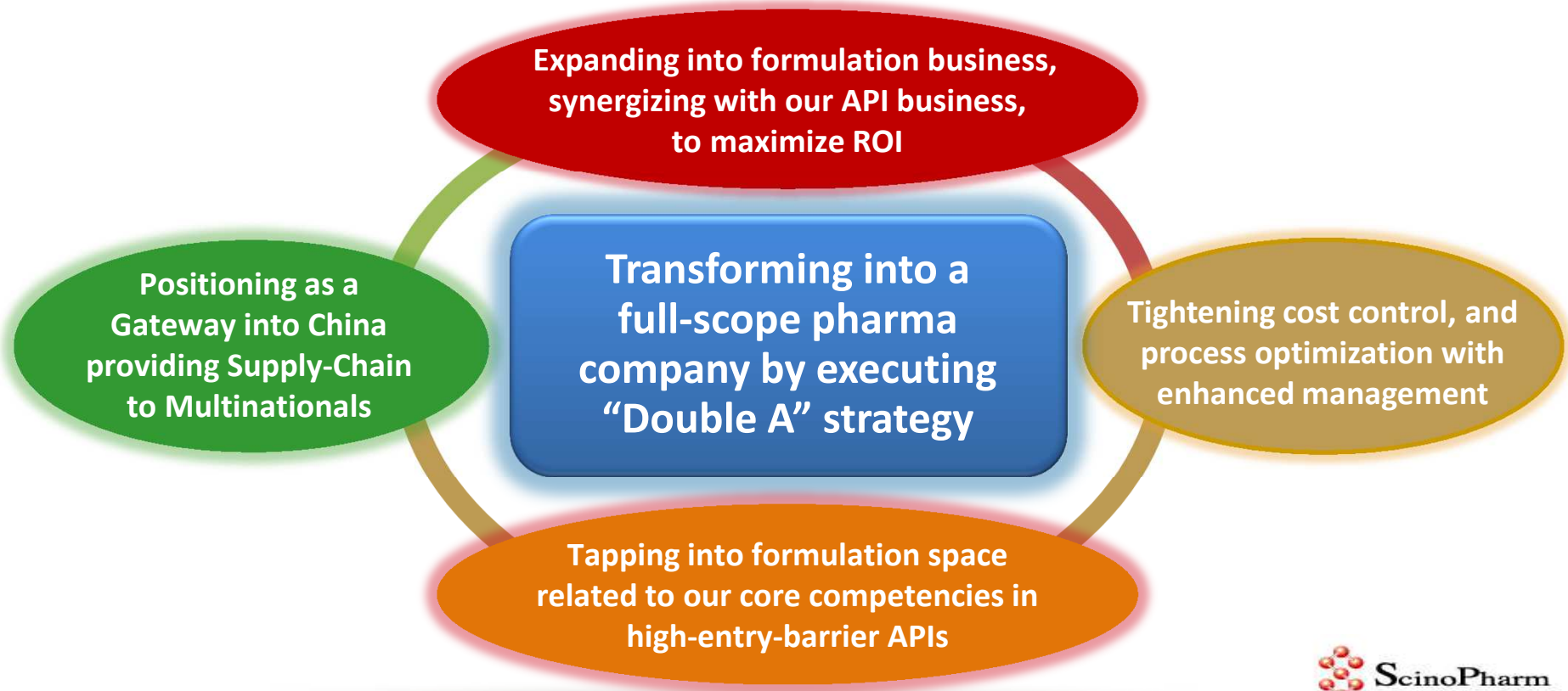
Transforming Our Business



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Keys to Generic Formulation Business

Opportunity	Strategy	Tactics
✓ Already the leader in providing oncology APIs to regulated markets worldwide ✓ Injectable CMOs are in short supply ✓ Can be customer's injectables provider by developing formulations using our own oncology APIs or others' APIs, up to and including ANDA filing with FDA	✓ Developing dossiers per our difficult-to-make APIs to increase value proposition in the supply chain ✓ Targeted delivery & extended release of proven APIs via 505(b)(2) fast track ✓ Collaborating with start-ups & research institutes, focusing on un-met oncology medical needs of high prevalence in Asia	✓ Expanding formulation portfolio ✓ Establishing on-site oncology injectable facility and providing an integrated supply chain ✓ Promoting our formulations via strategic alliances, especially in China and US/EU

Results

- **2 US ANDAs**
- **16 co-development 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 Virus	Taiwan	2013*	1st co-developed formulation product launch
Sagent	Oncology Injectable	Myeloid Leukemia	US	2018	1st US ANDA filing, triggering US FDA inspection in Changshu, China site
Foresee	Leuprolide	Prostate cancer	US	2019	505(b)(2) NDA CRAM + Equity
Coland	Bortezomib	Multiple Myeloma	China	2020	1st co-developed drug in China to trigger CFDA inspection in Changshu site
Lee's Pharma	Fondaparinux	Anti-thrombotic	China	2022	Co-development collaboration
	Travoprost &Bimatoprost	Glaucoma	China	2022	
Nanjing King Friend	Regadenoson	Stress agent for heart scan	China	2021	Co-developed formulation in China
US partner	Project A	Non-small cell lung cancer	US	2018	US NDA 505(b)(2) / The estimated launch year is subject to US FDA review
US & China partners	Project B	Imaging agent	US	2021	ANDA with Paragraph IV filing / The estimated launch year is subject to litigation results
Baxter	5 niche injectables	Anti-cancer & antinauseant	US/EU	2020& continuing thereafter	Baxter has the right to add up to 15 additional injectable products for collaboration
Indian Int'l partner	Fondaparinux	Anti-thrombotic	US/EU	2018	1st self-developed US ANDA submitted . Executive right for marketing & sales

In-House Injectable Plant Progress

- Taiwan-based facility will accommodate R&D, Quality Control, washing, sterilization, manufacturing, filling, lyophilization, packaging, and storage.
- Planned kick-off registration batch production by early 2018. Expected submission of 1st in-house ANDA in late 2018 and subsequent US FDA inspection approval in 2019
- Target products with high entry barrier or unit-pricing as in peptides and oncology agents.
- Offering CMO services for both brand and proprietary drugs


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Aseptic Fill & Finish Service

Vial Product Line Cytotoxic Injectable	Liquid Solution	Lyophilized Powder
Cartridge Product Line Peptide Injectable	Prefilled-Syringe	Pen Device

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Progress of Injectable Business

Product	Oncology Injectable	Fondaparinux	Others (10 drugs)
Partner	Co-development with Sagent	US-self development+local marketer CN-collaboration with Lee's Pharma	Self development and partnership
Formulation Production	Kindos Pharmaceuticals, China	CMO	CMO + In-house production
Type	Generic	Generic	New Drug/Generic
Indications	Myeloid Leukemia	Anti-thrombotic	Cancer, diabetes, osteoporosis, multiple sclerosis and antinauseant
Market Size	US: US$200M	US:US$100M/CN:US$80M	
Launch Year(E)	2018	US:2018/CN:2020	After 2020

CRO Phase III Product Portfolio

Est. NDA Filing Year	Indication	Region	Remarks
2018	Type I,II Diabetes	US/ EU	Intermediate project made in Changshu site. Expected revenue of several million USD per year after launch
2018	Advanced Hepatocellular Carcinoma, Myelofibrosis, Autoimmune disease, etc.	CN	API project made in Changshu site. CFDA granted accelerated review under its category 1.1 innovative drug. Anticipated launch in 2019 with demand in tons
2018	Prostate Cancer	US / EU	Started process validation. Anticipated launch in 2019 and revenue of several million USD per year

Emerging and Japan Market Development

China

- Accelerate progress to create positive cash flow
- Focus on mid- to late-phase CRO projects. Current portfolio includes agents for oncology, anti-hypertension, and diabetes
- Seek generic APIs/intermediates with large demand to increase production utilization

Japan

- Among 20 customers, 6 are top 10 drug firms. Less established players have exited the more concentrated market
- Encourage local generic customers to engage more in direct business
- Support Japanese companies and foreign pharmaceutical companies to enable and extend business outreach

Capturing Chinese Growth on Multiple Fronts

- MNCs and emerging virtual-model players create a sizable demand in high-quality and compliant API contract manufacturing in China
- Existing review and approval mechanisms significantly raise the entry barrier and cost structure in the Chinese drug market, requiring dedication to quality and innovation
- We have domestic presence plus world-class strength in:
    - * Global, first-tier customer base
    - * High-technical-barrier oncology APIs
    - * Quality and EHS/GMP compliance

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 / CMO	>15 projects, including brain tumor, antibiotic, hypertension, eye drops, 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
Aslan Pharmaceuticals	CRO	Phase II clinical trial for cancer	API	China/Global
Top 5 global pharma	CRO	Phase III 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
US-based new drug company	CRO	Phase I clinical trial for sickle cell disease	API	US

Maintain Market Share of Existing APIs

- 2016 Major Products account for 65% of total sales

API Product	Indication	2016 MKT share*	# of US DMF/EDMF & other filings
Irinotecan HCl	Antineoplastic	42%	63
Paclitaxel	Antineoplastic	34%	57
Gemcitabine	Antineoplastic	24%	76
Exemestane	Antineoplastic	22%	44
Galantamine HBr	Antipsychotic	17%	38
Docetaxel Anhydrous	Antineoplastic	15%	69

*Source: IMS data from Newport

Operating Results & Business Updates

P&L - Consolidated

In NT$ million, except for EPS	1Q~3Q,'17 (Reviewed)	1Q~3Q,'16 (Reviewed)	YoY
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	

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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%*

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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
CAPEX	(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

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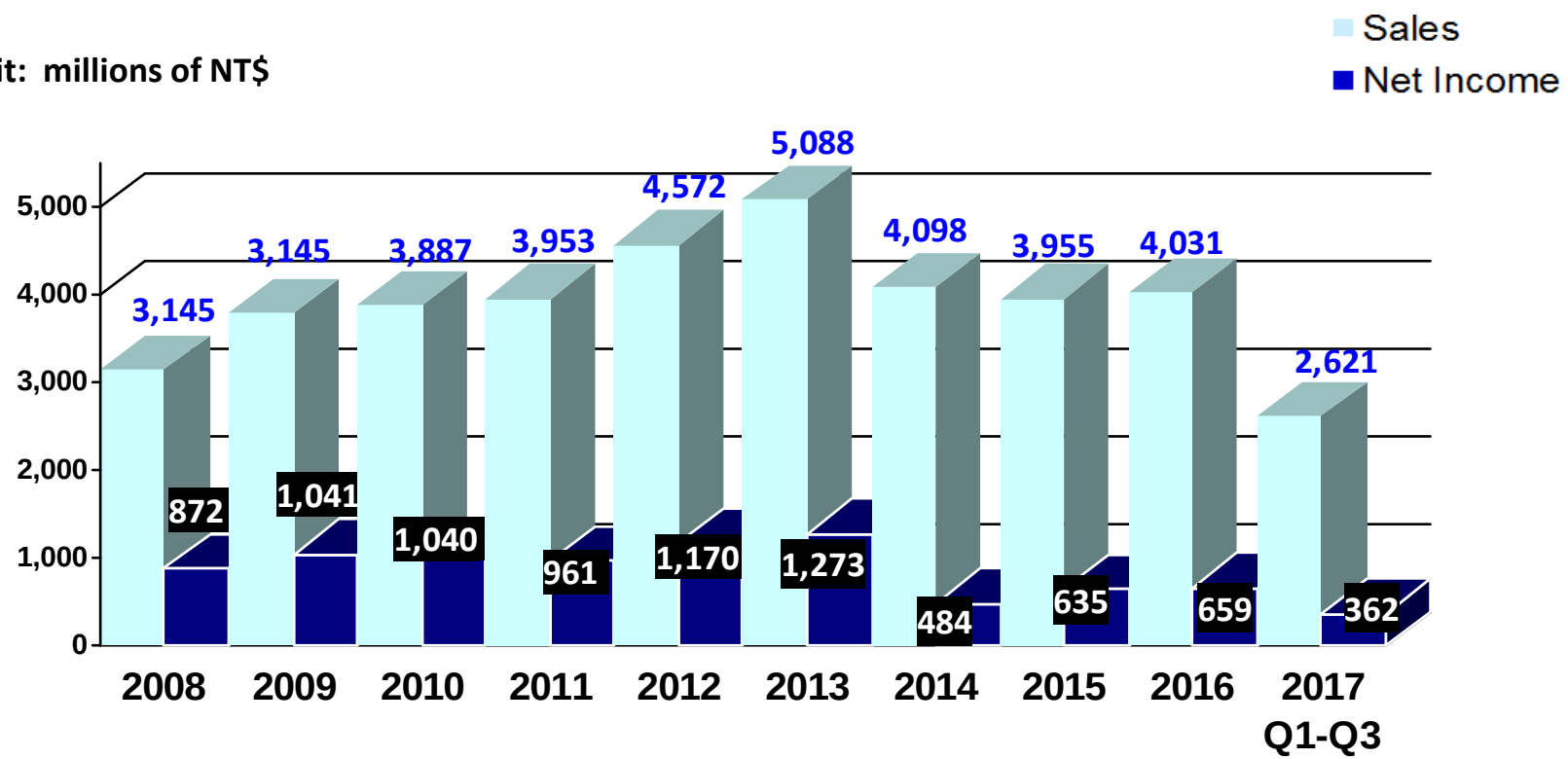
Historical Performance

Unit: millions of NT$



Recent Financials

In NT$

Year	2013	2014	2015	2016
Total assets	11,484 M	11,372 M	12,222 M	12,783 M
Shareholders' equity	9,643 M	9,380 M	9,857 M	10,228 M
Sales	5,088 M	4,098 M	3,955 M	4,031 M
Net profit after tax	1,273 M	484 M	635 M	659 M
Earnings per share	1.88	0.69	0.87	0.87
Cash dividends	1.2	0.2	0.3	0.3
Stock dividends	0.4	0.4	0.4	0.4
Pay-out ratio	85%	87%	80%	80%

Note : All of the above figures represent consolidated information

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Injectable Products Allied with Baxter

- ScinoPharm and Baxter Healthcare establish worldwide partnerships to co-develop and commercialize five niche generic injectable products at the initial stage
- ScinoPharm develops all APIs and injectable formulations. Baxter leads regulatory submissions in the US/EU and eventually market & sell the injectable products via its extensive presence in the hospital channel
- Both parties work on a cost-and-profit-sharing collaboration model
- Baxter has the right to add up to 15 additional injectable products for collaboration with ScinoPharm

Collaboration Framework

- Initial product portfolio including the generic injectables for breast cancer, lung cancer, multiple myeloma and antinauseant. Targeting US/EU markets first and expect to expand to other territories
- This exclusive partnership will utilize each other's strengths and expertise in order to achieve large scale of synergies in providing niche and affordable generic injectable products
- Commercial launch for the first 5 products upon FDA approval, with product launches beginning in 2020 and continuing thereafter
- Current branded sales of the initial five products included in this partnership total more than $4 billion annually

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Responsibilities by ScinoPharm and Baxter

API Development

API Production

Formulation Development

ScinoPharm

FDF Manufacturing

ScinoPharm
Baxter
CMO

Sales & Marketing

Baxter

Benefits of the Collaboration

- Aggressively expanding our “Double A” strategy for in-house developed/produced APIs and formulations. Providing an outlet for our injectable plant capacity
- A win-win solution and collaboration. ScinoPharm provides comprehensive APIs and formulation portfolio, while Baxter operates strong injectable product marketing channels throughout the US and worldwide
- Accelerate the momentum of our downstream integration strategy by establishing alliance with an world-renowned partner

2017 Product Launch Plan

Type	Product	Region	Indication	Brand Marketer	Regional Sales	WW Sales
✔ 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	Oral Product	USA EU	Antibiotics	N/A	N/A	N/A
Generic Drug	Oncology Injectable	US	Myeloid Leukemia	MDS	US$183M	US$278M

Source: IMS Data (2015Q3-2016Q2)

✔ Launched

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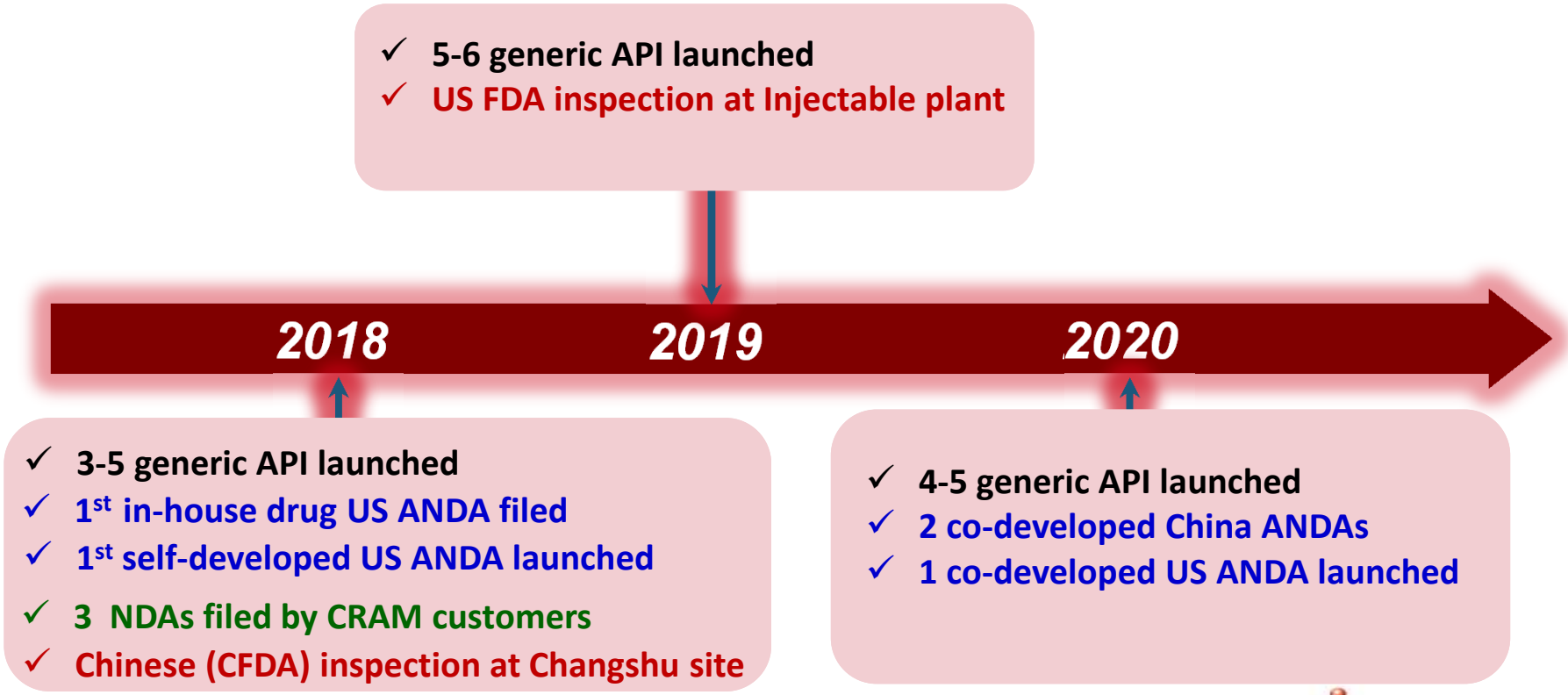
Pipeline Outlook Timeline



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Brand Quality with Asian Advantages

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