ScinoPharm

TWSE 1789

ScinoPharm Management Presentation

2016/07/20

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Overview of ScinoPharm

Background

- Established in 1997 in Taiwan and listed on TWSE in 2011
- Major shareholders include Uni-President Group, National Development Fund, & Taiwan Sugar
- Facility & organization built in Taiwan by experienced Syntex team, received multiple regulatory inspections from US FDA, Australia, EU, Japan, etc.
- Specializes in high potent/cytotoxic APIs & moves to injectable formulations
- Expanding in China with a marketing base in Shanghai & new GMP plant in Changshu, just inspected by US FDA with zero 483

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World Class API Facilities

Taiwan

- 6.6 hectares of land, 330K sqft facilities with >200M^3 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

China

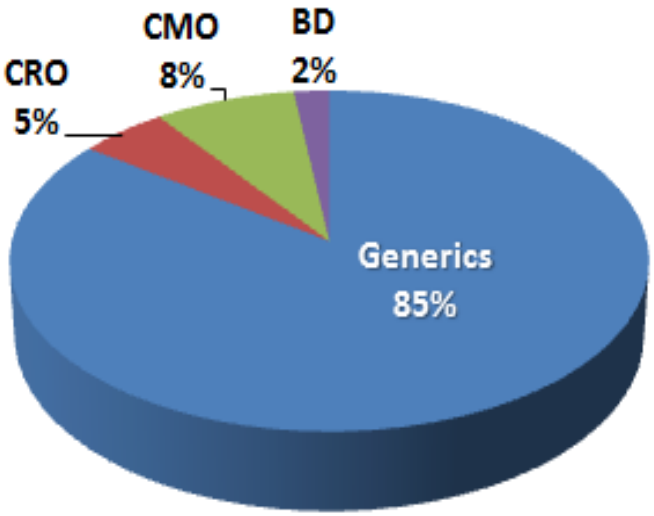
- 6.5 hectares of land with > 250M^3 reactor volume
- 3 of 7 production lines equipped with high potency capabilities for cytotoxics
- US FDA approved cGMP facility for intermediates & high potency API
- Full scope capabilities in developing and producing APIs from small to large scale for generic &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

Business Overview

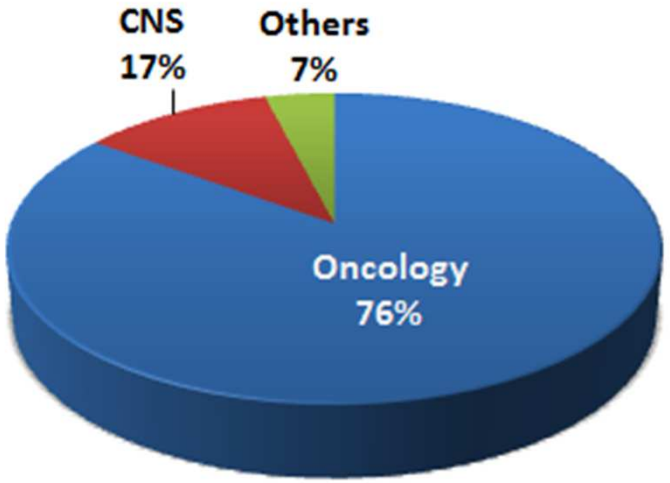
- Risk & return balanced model to offer APIs and sterile filling capability for both generic and new drugs
- 70+ generic APIs in current portfolio with 25 APIs launched; 50 US DMFs filed (737 DMFs WW), 30 US DMFs in oncological APIs
- 100+ NCE CRAM projects, with 5 launched and 5 in phase III for NDA filing in 2-3 years; The Qualified Asian supplier to provide APIs to global market for multiple commercial NCEs

2015 Sales Distribution

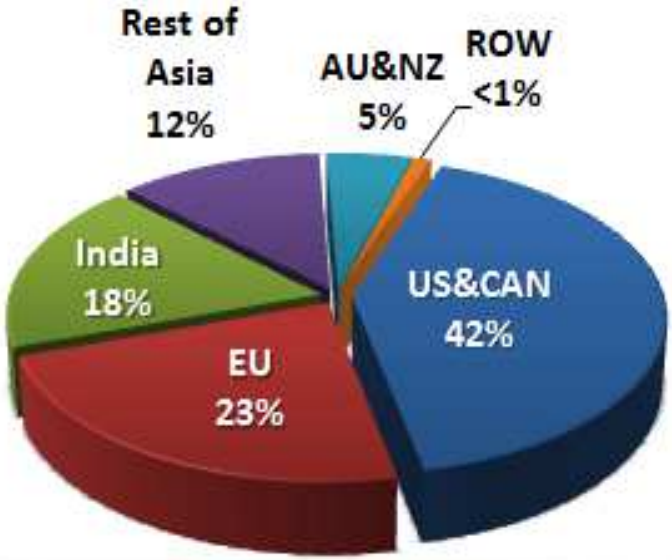
By Business



By Indication



By Region



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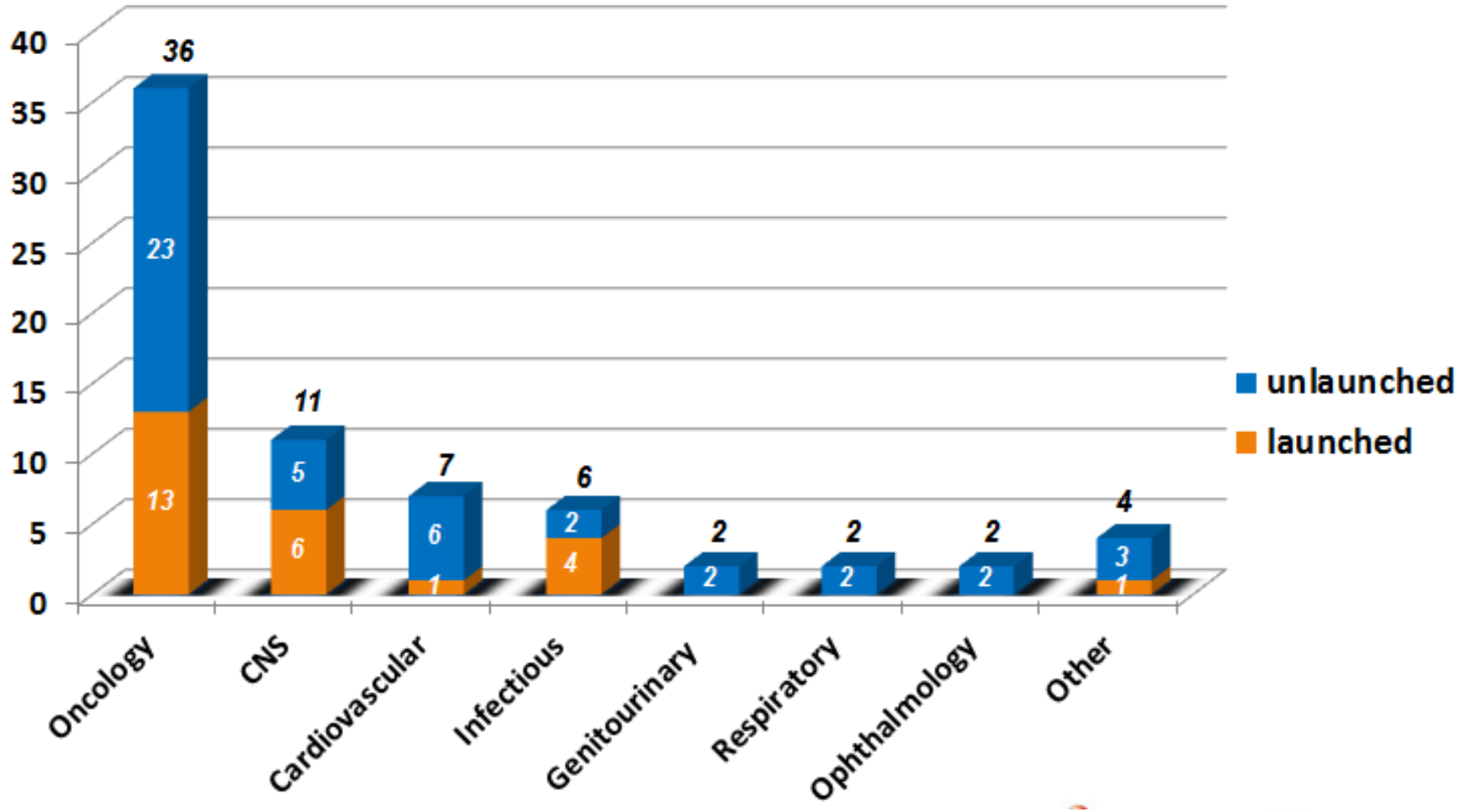
Strong Generics Product Portfolio



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

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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

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Strategies and Opportunities

Long Term Strategies

Transforming to a full-scope pharma company per our core competency of R&D and cGMP manufacturing in high-technical barrier APIs

- **Vertical Integration to Generic Formulations: Developing dossiers per our difficult-to-make APIs to increase value proposition in the supply chain**
- **Innovative Delivery Formulations: Targeted delivery & extended release of proven APIs via 505(b)2 fast track**
- **Brand New Chemical Entities (New Drugs): Collaborating with start-ups & research institutes, focusing on un-met oncology medical needs of high prevalence in Asia**

Keys to Generic Formulation Business

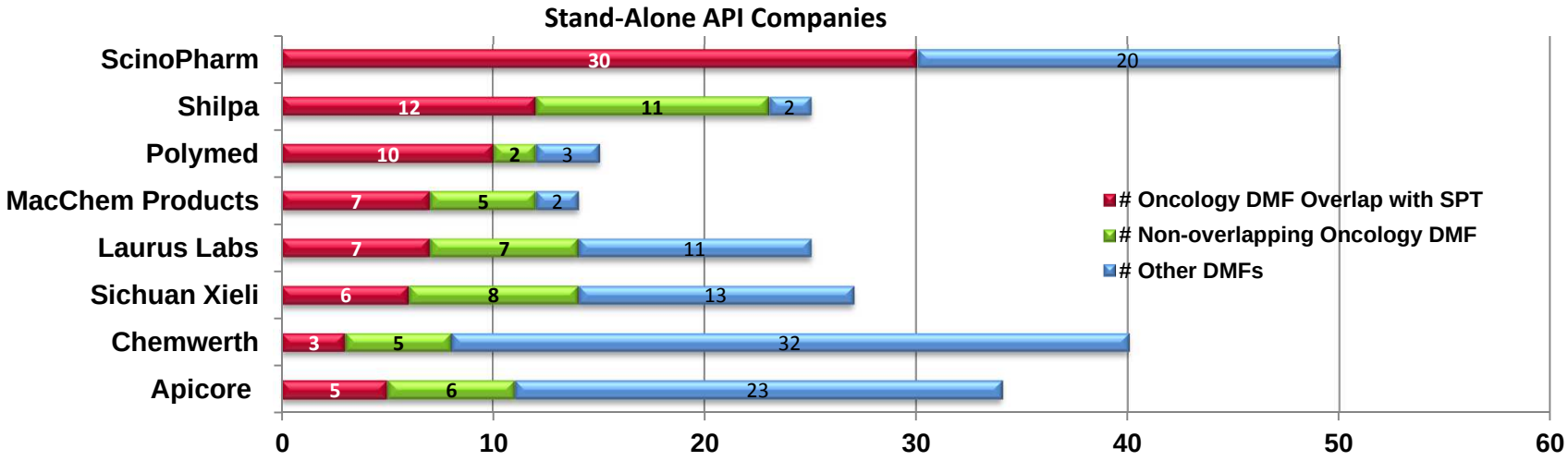
- Expanding formulation portfolio
- Building on-site oncology injectable facility and establishing a complete supply chain
- Sustaining B2B model, promoting our formulations via strategic alliance, especially in China and US/EU
- Acquiring critical resources via M&A

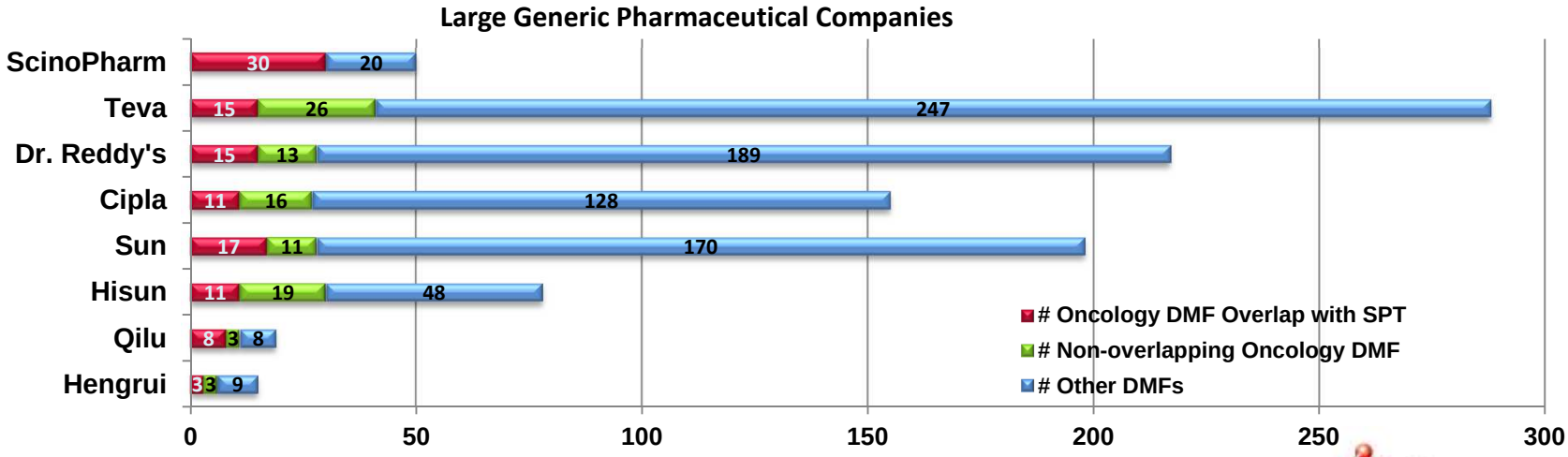
Strategic Alliance Highlights

* Already launched

Partner	Product	Indications	Region	Launch Year(E)	Remarks
Genovate	Entecavir	Hepatitis B Viral	Taiwan	2013*	1st co-developed formulation product launch
Sagent	Oncology Injectable	Myeloid Leukemia	US	2017	1st 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	1st 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

ScinoPharm - Oncology API Leader





Source: US FDA 2016 Q1

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ScinoPharm Changshu Operating Update

The Completive Advantages

Process Development Capability

Collaborating with a partner specialized in enzymatic technology to integrate with ScinoPharm in-house strong chemical synthesis capabilities for providing services to develop greener, safer, and more cost-effective API manufacturing processes

GMP Production Capability

Knowledge to design, develop, and test parameters of spray drying process for APIs which are difficult-to-dry, are sensitive to long drying residence time, or require uniform particle size distribution

Regulatory Compliance Capability

Fully compliant with the most advanced guideline published by EMA in 2014 to set the standards for production line segregation and equipment cleaning criteria

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Operating Progress

- Actively implementing more than 20 contract research or manufacturing projects every year
- 9 US/EU customers and 3 of them are top 10 big pharmas
- Strategically partnership with Lee's Pharma in China to provide API process development and manufacturing services for more than 15 projects
- Successfully passed 14 GMP and 2 EHS audits conducted by customers

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Selected List of CRAM Projects at SPC

No	Customer	Project Type	Product Indication/stage	Product Type	Remarks/ Market
1	Top 10 global pharma	CMO	Approved antidepressant drug in US	GMP Intermediate	Passed Mexican authority (APIF) GMP inspection
2	Top 5 global pharma	CMO	Approved African sleeping disease drug	API	Site transfer from SPT
3	Lee's Pharma	CRO	+15 items including topical anesthetic, brain tumor, antibiotic, hypertension, eye drop, etc.	API	China
4	China pharm company	CRO	Phase II/ III clinical trial for cancer	API	China
5	China pharm company	CRO	Phase IIb for age-related macular degeneration	API	US/China
6	Taigen Biotech	CRO	Phase II clinical trial for myocardial infarction	API	China/Taiwan
7	US-based new drug company	CRO	Phase II clinical trial for prevention of HIV infection	API	US
8	Alsan Pharmaceuticals	CRO	Phase II clinical trial for cancer	API	China/Global
9	Top 5 global pharma	CMO	Phase II clinical trial for diabetes	Intermediate	US
10	Top 5 global pharma	CRO	Phase I clinical trial	API	NA
11	US NASDAQ listed pharma	CRO	Phase III clinical trial for opioid-induced constipation	Crude API	US

Key Progress for China Market

ScinoPharm Taiwan

Submitted drug import license applications for 12 APIs (anti-cancer, cardiovascular, Alzheimer's disease, benign prostatic hyperplasia, hepatitis B, etc.)

ScinoPharm Changshu

- Obtained drug production permits for 11 APIs for anti-cancer, anti-viral, glaucoma, etc.)
- Submitted 5 drug license applications for USFDA, 1 for EDQM and 2 for CFDA

Strategic Alliance

5 formulation development and 1 new drug projects smoothly undergoing. Expected to be commercially available in 2019-2022

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ScinoPharm Outlook

2016 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

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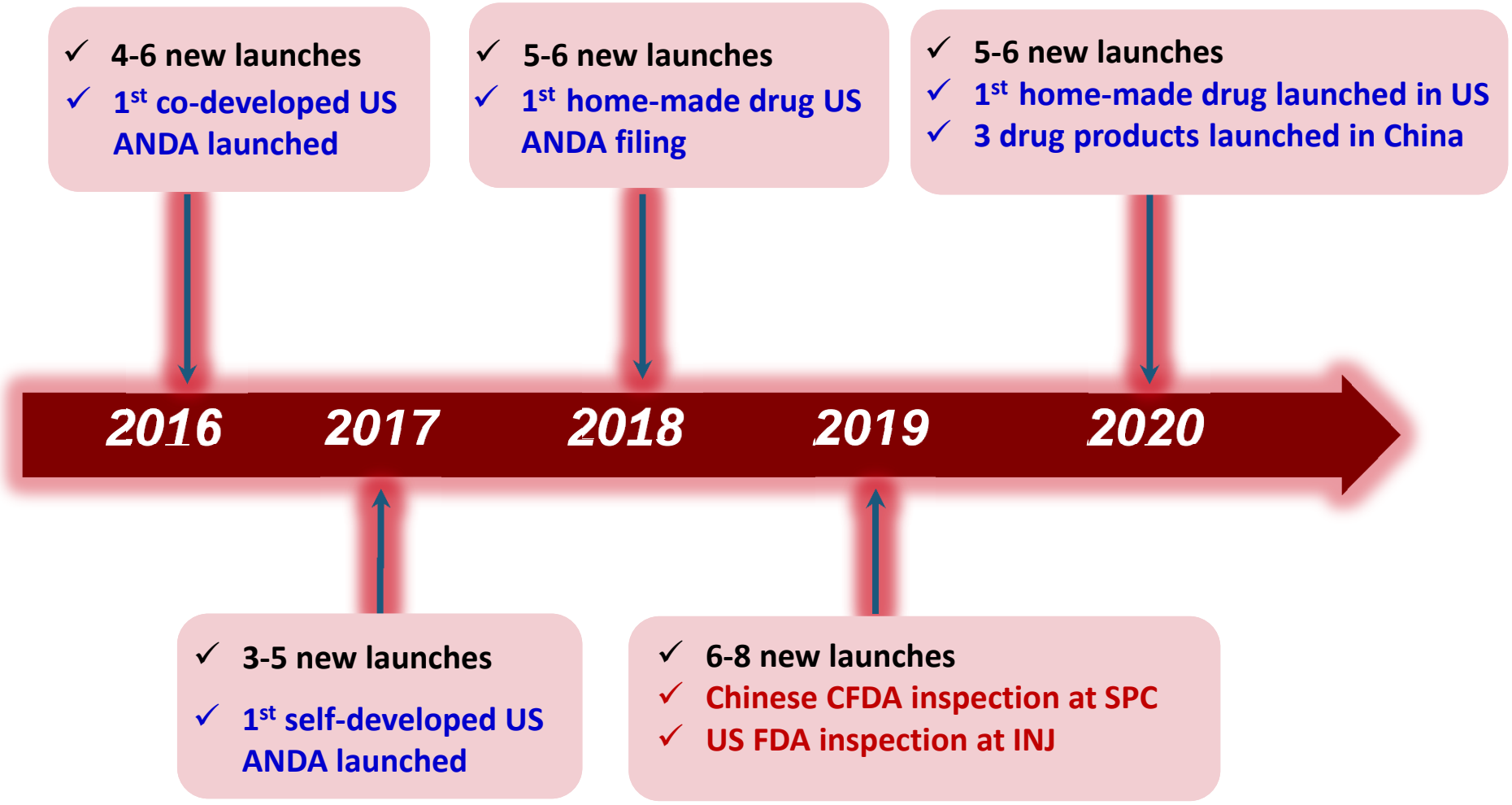
Pipeline Outlook



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Brand Quality with Asian Advantages

www.scinopharm.com