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ScinoPharm

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Overview

ScinoPharm at a Glance

- Est. in 1997 in Taiwan (Tainan) with cGMP plants/R&D in Tainan and Changshu and marketing forces in Tainan, Shanghai and Tokyo
- Specializes in high potency (cytotoxic/steroid) API and injectable R&D and manufacturing with customers worldwide
- 73 generic APIs in portfolio with 31 referred and approved by ANDA/NDA*
 - 62 active US DMFs (833 DMFs WW) with 37 oncology APIs*
- 150+ contract projects with 7 approved/launched (5 NCEs) and 8 in phase 3 for NDA/MAA 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

* Data as of 2020/02/29

2019 Achievements (I)

- Tainan site passed the US FDA's 7th inspection in May 2019, without 483
- 2019 Approved Products

Type	Product	Region	Indication	Brand Marketer
Generic API	Docetaxel Trihydrate	US	Various cancers	Sanofi Aventis
Generic API	Tamsulosin HCl	US	Benign prostatic hyperplasia (BPH)	Sanofi Aventis
Generic API	Flumazenil	JP	Benzodiazepine antagonist	Genentech
Generic Drug	Fosaprepitant	US	Antiemetic agent	Merck
CDMO API	Intermediate for a NCE	EU	Metabolism	CRAM Customer

2019 Achievements (II)

■ Japan Market Expansion

- Capecitabine launched in January, 2019
- Flumazenil approved in November, 2019

■ Injectable Business Progress

- Fosaprepitant approved by US FDA in September, 2019 and launched in November, 2019
- Fondaparinux Sodium PFS shipped to USA in November, 2019
- Exhibit batches of the first in-house product in prefilled syringe format completed
- Site Acceptance Test (SAT) of vial line completed



Business Outlook

Business Strategies

**Advancing to
Injectables**

**Optimize
Existing Generic
API Portfolio**

**Expand CDMO
Business**

Actively Develop Japan, China and Emerging Markets

Advancing to Injectables



APIs



Oral Solids
Immediate Release



Oral Solids
Extended Release



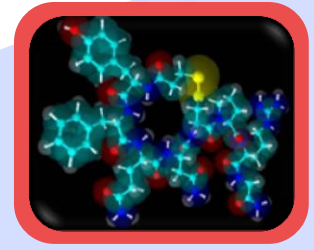
Dermatological
Semi-Solids



Sterile
Injectables



Otics & Ophthalmics



Peptides



Pen Injectors



Respiratory Devices

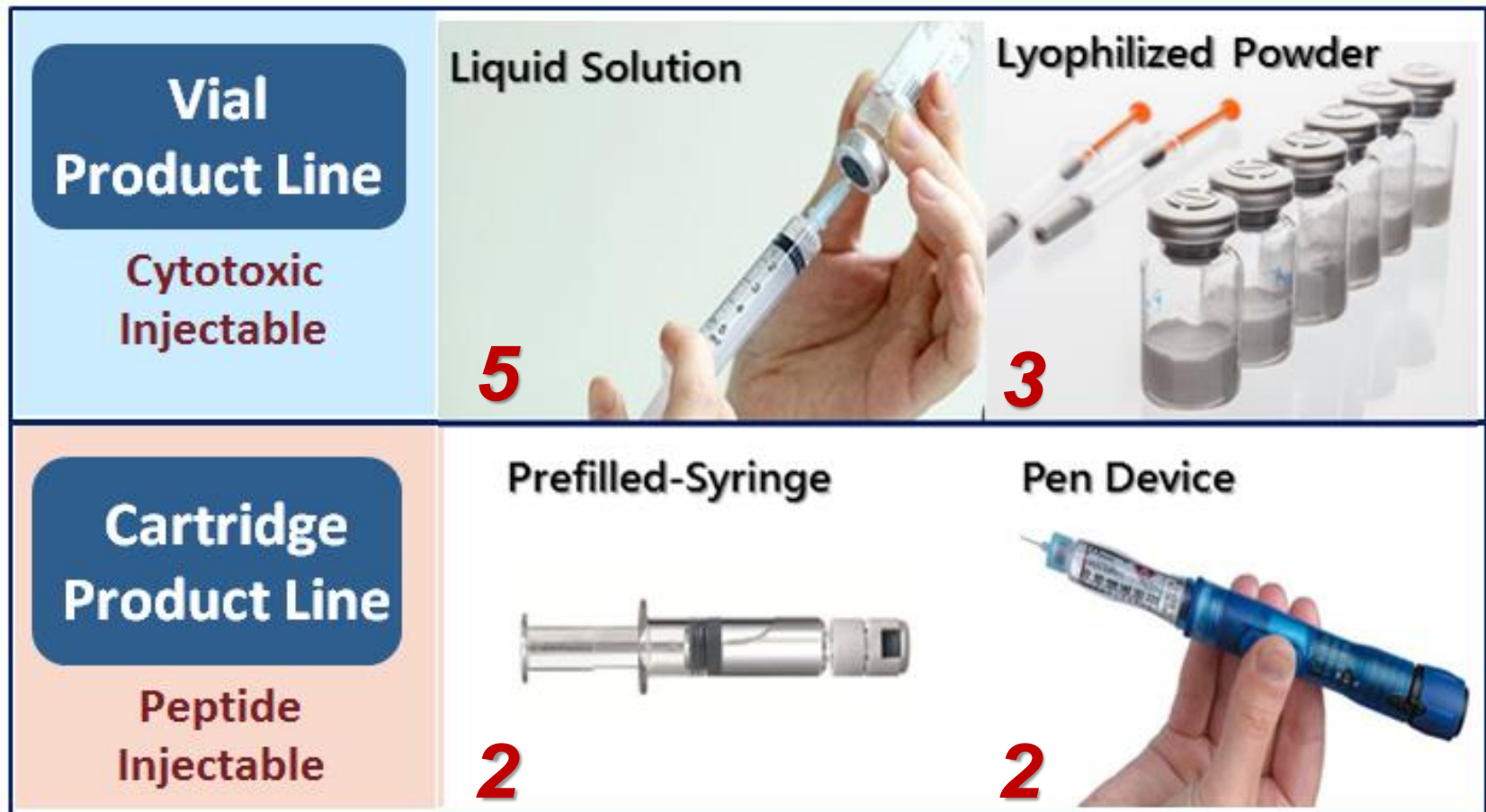
Higher entry barriers due to more tech, IP and regulatory requirements lead to more value

2020 Injectables Targets

- **Fondaparinux Sodium PFS launched in USA in February, 2020**
- **Twelve products under development with target to complete registration batches for five products in 2020**
- **Aim to trigger TFDA on-site inspection**
- **Expect to submit the 1st in-house produced ANDA**

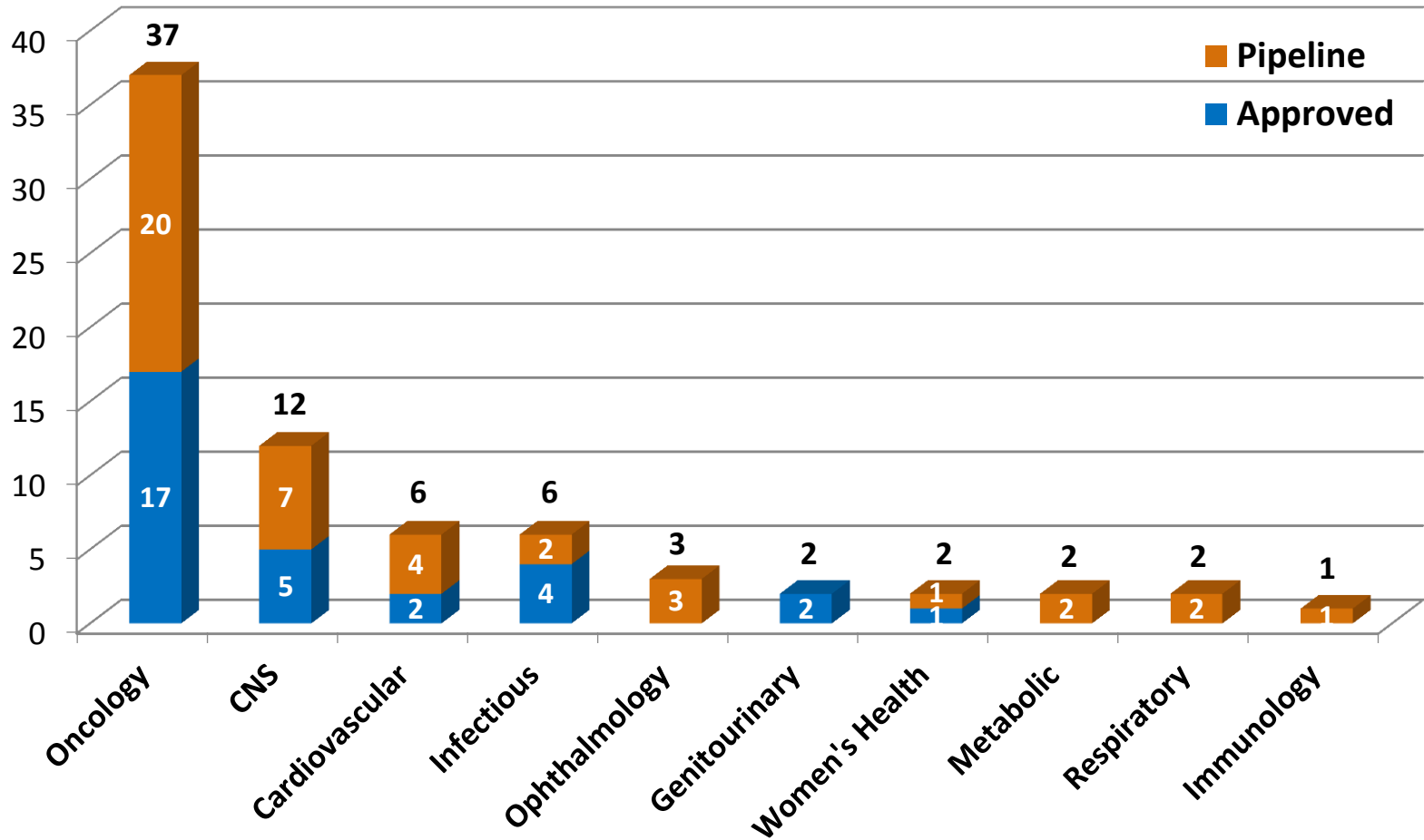
In-House Injectables Portfolio

- Twelve products under development with target to complete registration batches for five products in 2020



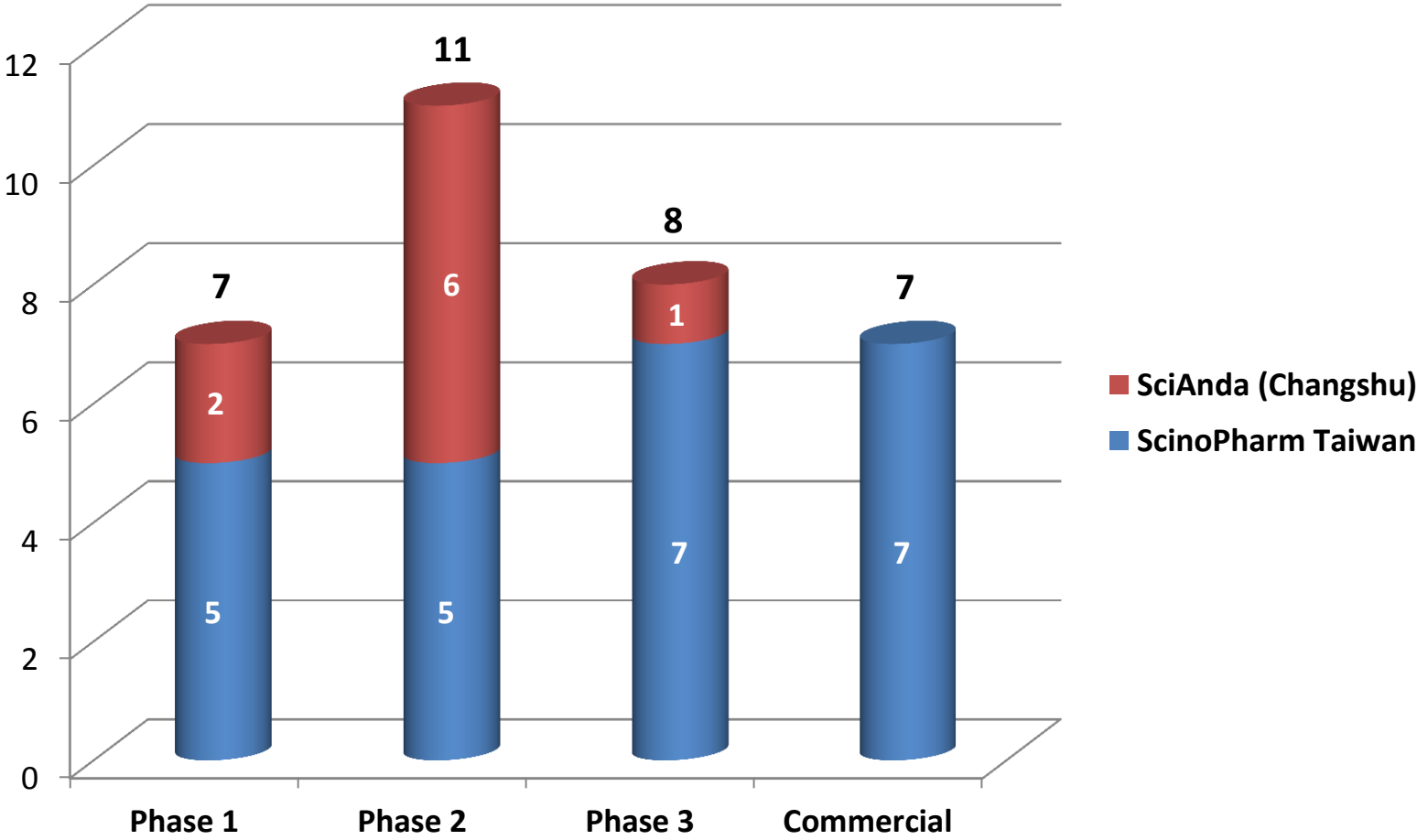
Data as of 2020/02/29

Optimize Existing Generic API Portfolio



Data as of 2020/02/29

Expand CDMO Business



Data as of 2020/02/29

Actively Develop Japan, China 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 business and leverage new capabilities of injectables
- 15 approved JMF of Generic APIs

■ China

- Expand new API business under MAH new regulation
- Develop API portfolio for China market
- Focus on FDA/CFDA Dual Filing Customers
- 20 Chinese customers with 8 targeting at Dual Filings



2020 Product Approval Plan

2020 Product Approval Plan (I)

Type	Product	Region	Indication	Brand Marketer
Generic API	Capecitabine	CN(✓)	Various cancers	Roche
Generic API	Dantrolene Sodium	CN	Skeletal Muscle Relaxant	Par Sterile Products
Generic API	Tamsulosin HCl	CN(✓)	Benign prostatic hyperplasia (BPH)	Sanofi Aventis
Generic API	Fondaparinux Sodium	CN	Anti-thrombotic	Mylan
Generic API	Anastrozole	CN	Breast cancer	ANI Pharmaceuticals
Generic API	Sodium Phenylbutyrate	CN	Urea cycle disorders	Horizon Therapeutics
Generic API	Azilsartan	CN	Hypertension	Arbor Pharmaceuticals

✓ : Approved

2020 Product Approval Plan (II)

Type	Product	Region	Indication	Brand Marketer
Generic API	Galantamine HBr	JP(✓)	Alzheimer's disease	Janssen
Generic API	Topiramate	JP	Anti-convulsant	Janssen
Generic API	Topiramate	EU	Weight management	Vivus
(*)Generic API	Pemetrexed Disodium 7H ₂ O CEP	EU	Non-small cell lung cancer	Eli Lilly
Generic API	Fulvestrant	US	Breast cancer	AstraZeneca
CDMO API	Donafenib	CN	Anti-cancer	Suzhou Zelgen
CDMO API	Quofenix	EU(✓)	Anti-biotic	Melinta

✓ : Approved

* : Collaborative project with partner for drug product development

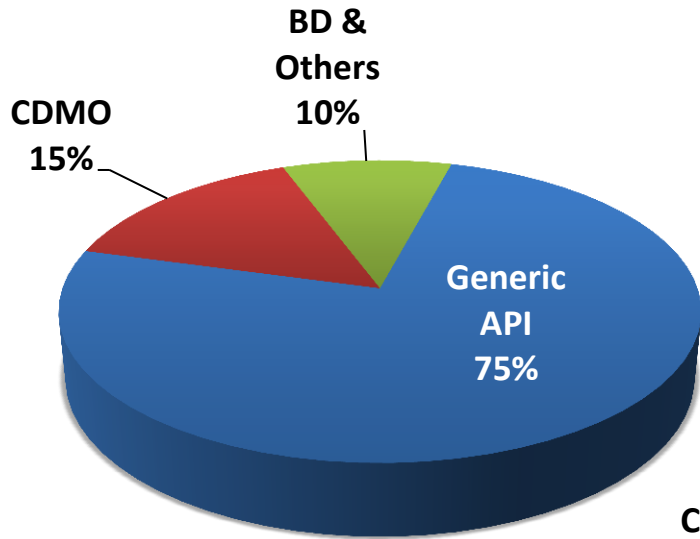


Operating Results

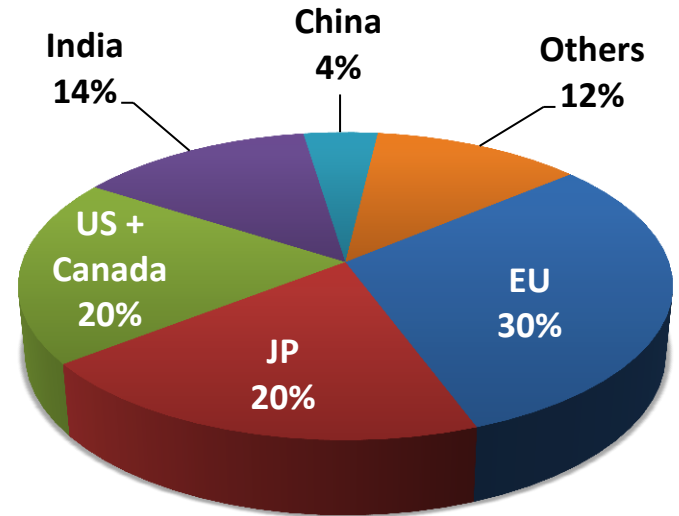
Consolidated Income Statement

In NTD Million, except for EPS	2019 (Audited)		YoY	2018 (Audited)	
Revenue	2,893	100%	-18%	3,524	100%
Gross Profit	1,176	41%	-24%	1,543	44%
Operating Profit	267	9%	-52%	558	16%
Net Profit before Tax	265	9%	-46%	491	14%
Net Profit after Tax	217	8%	-51%	443	13%
EPS (NTD)	0.27	-	-	0.56	-

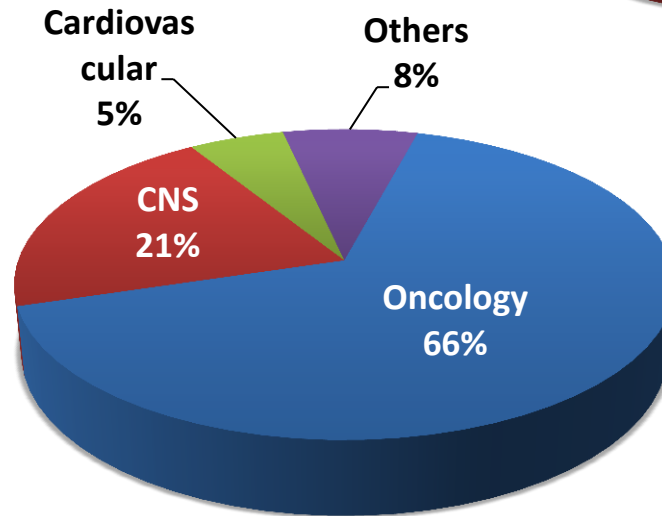
2019 Sales Distribution



by Business



by Region



by Indication

Sales Distribution – YoY

By Business

Unit: USD

	Generic API	CDMO	BD & Others
2019 Sales	70.4M	14.1M	9.2M
YoY	-6.5%	-64.3%	331.5%

By Indication

	Oncology	CNS	Cardiovascular	Others
2019 Sales	62.0M	19.4M	5.1M	7.2M
YoY	-5.1%	17.3%	77.3%	-77.7%

By Region

	EU	Japan	US & Canada	India	China	Others
2019 Sales	28.6M	18.8M	18.4M	12.7M	4.0M	11.2M
YoY	-28.7%	108.1%	-62.7%	9.1%	403.4%	80.6%

Consolidated Balance Sheet

In NTD Million	2019 (Audited)		2018 (Audited)	
Cash and Cash Equivalents	3,305	28%	4,203	34%
Accounts Receivable	590	5%	559	4%
Inventories	1,124	10%	1,364	11%
Property, Plant & Equipment	4,434	38%	4,759	38%
Other Current/Non-Current Assets	2,222	19%	1,678	13%
Total Assets	11,675	100%	12,563	100%
Financial Debt	234	2%	1,412	11%
Other Current Liabilities	508	4%	534	4%
Other Non-Current Liabilities	673	6%	78	1%
Total Liabilities	1,415	12%	2,024	16%
Total Shareholders' Equities	10,260	88%	10,539	84%

Consolidated Cash Flow Statement

In NTD million	2019 (Audited)	2018 (Audited)
From Operating Activities	789	1,231
From Investing Activities	(98)	(300)
From Financing Activities	(1,572)	(627)
Effect of foreign exchange rate changes	(17)	(12)
Net Change in Cash	(898)	292
Beginning Balance	4,203	3,911
Ending Balance	3,305	4,203



Q & A



Brand Quality with Asian Advantages

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