



台耀化學股份有限公司

Formosa Lab

Performance and Business Outlook

TWSE 4746

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Index

- ◆ Introduction
- ◆ Strategy and Execution
- ◆ Business Outlook
- ◆ F/S- Sales from Jan~Feb, 2015 、 F/S of 2014Q3



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Introduction

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- Established on Dec. 29, 1995
- Capital : NTD 840 million
- Employee headcount : 561 persons
- Area : 45,508 m²
- Business scope : APIs (34 US DMFs)
UV filter (One of top three makers)
Contract API RD & Manufacturing
- Inspected by Taiwan TFDA, US FDA, Japan PMDA, German BGV
and EU EDQM

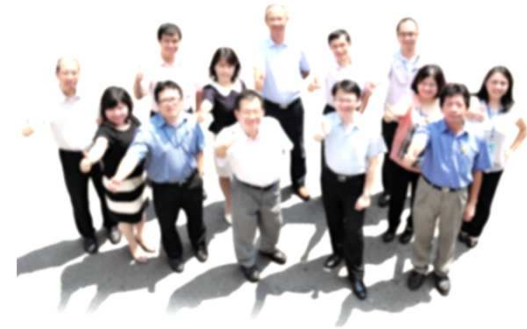




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Strategy and Execution

Business Strategy

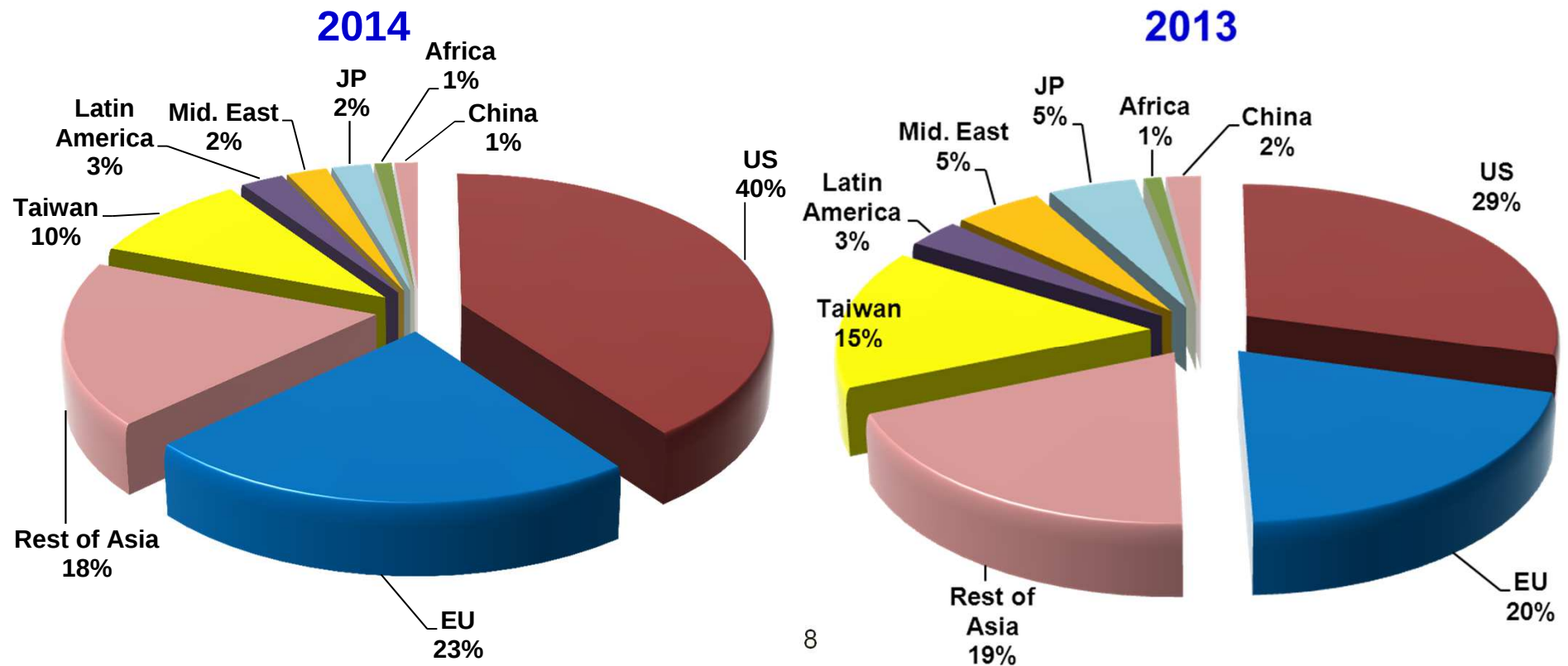


- Committed to providing qualified products and services with international standard of operation
- Develop and facilitate technology platform and manufacturing capacity for products with high entry barrier
- Engage early phase development projects and innovative technology



International Standard

- Facility has been approved by TW FDA, US FDA, PMDA, German BGV and DEQM



Commitment in Innovation

NT\$ MM	2011	2012	2013	2014 Q3
Capital	671	671	841	844
Operating revenue	2,626	2,524	2,474	1,971
RD expenses	142	172	194	131
RD expenses / Capital	21%	26%	23%	16%
RD expenses / Operating revenue	5%	7%	8%	7%
RD Personnel	54	55	57	58

Recent Capacity Expansion

● Cholesterol/ Phosphate Binders manufacturing facilities(Plant E)

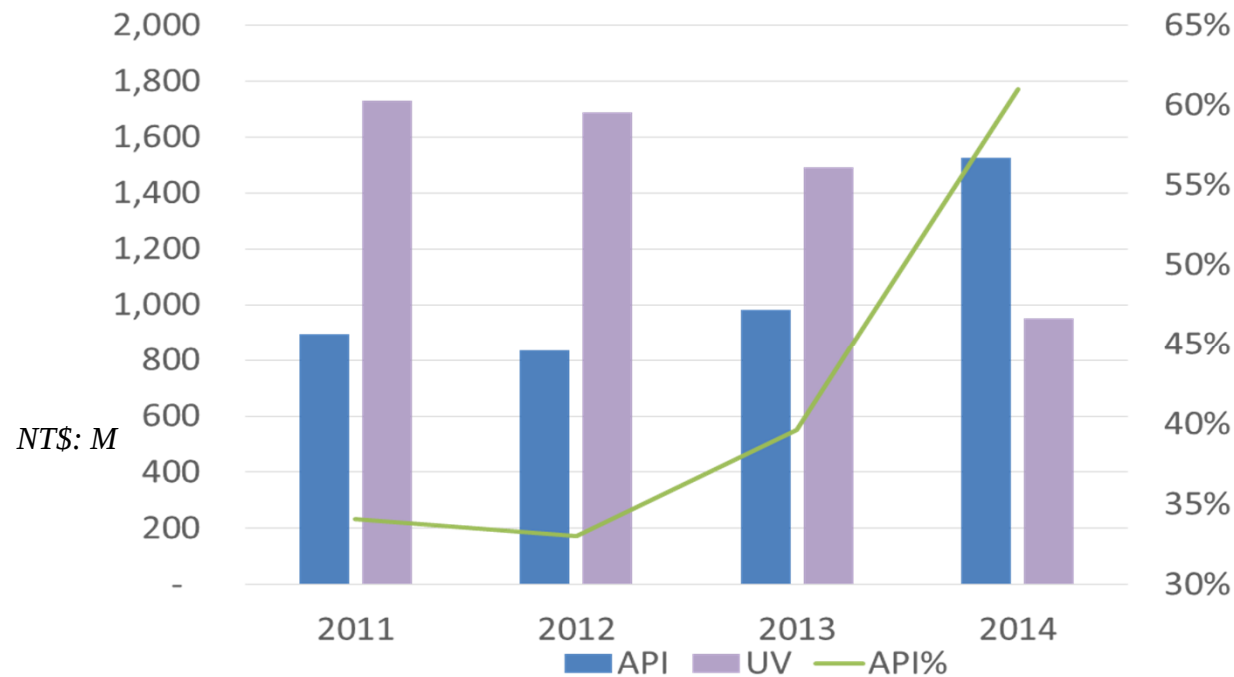
- 2010-2013Q4
- US\$35M Investment
- 500tons manufacturing capacity for Sevelamer HCl/ Sevelamer carbonate and Colesevelam, agents for hyperphosphatemia and hyperlipidemia management
- 900tons of API demand before patent-off, which occurs in 2014-2015 in DM
- Limited qualified suppliers

● High Potency Plant Expansion(Plant D1)

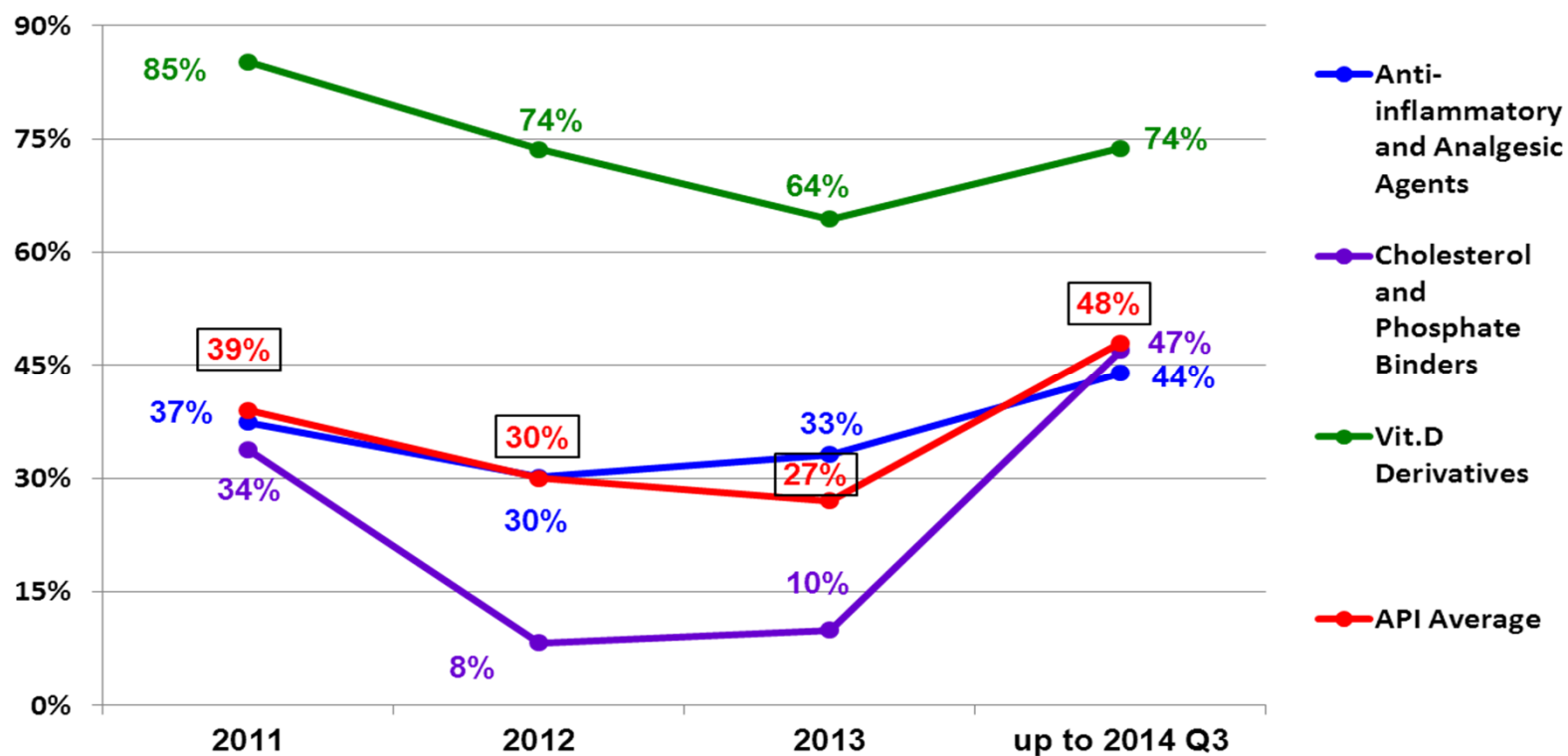
- 2014-2016e
- US\$22M Investment
- Facilities for products with high entry barriers, Vitamin D derivatives, cytotoxic agents for cancer treatment, hormones, and antibody-drug conjugates
- Limited qualified suppliers

Product Mixture in Transition

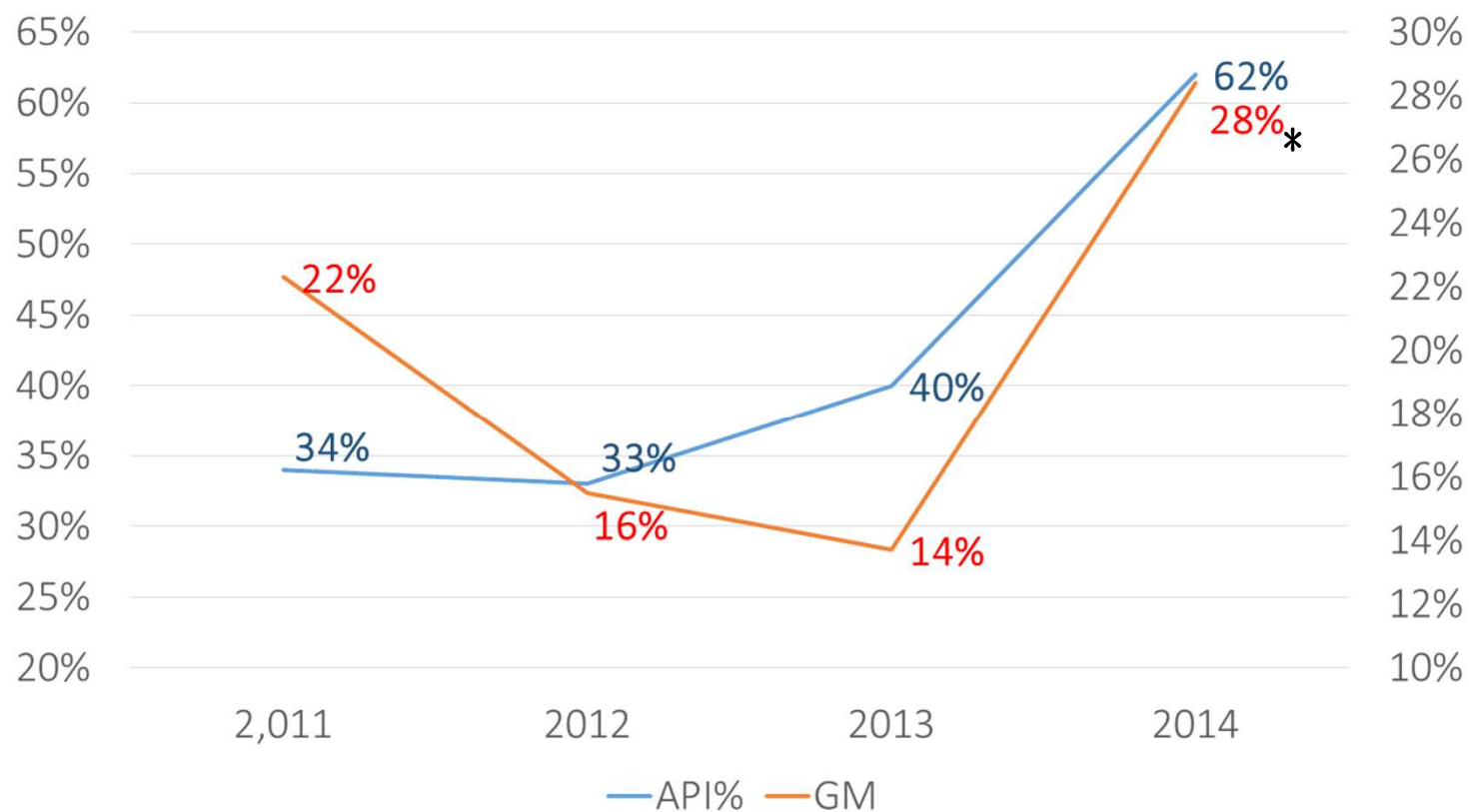
- Growth momentum comes from introduction of new API capacity and products lines, YoY from 2013-2014, +59%
- UV filter products sales drop significantly, YoY from 2013-2014, -36%



Efficiency in Transition-API

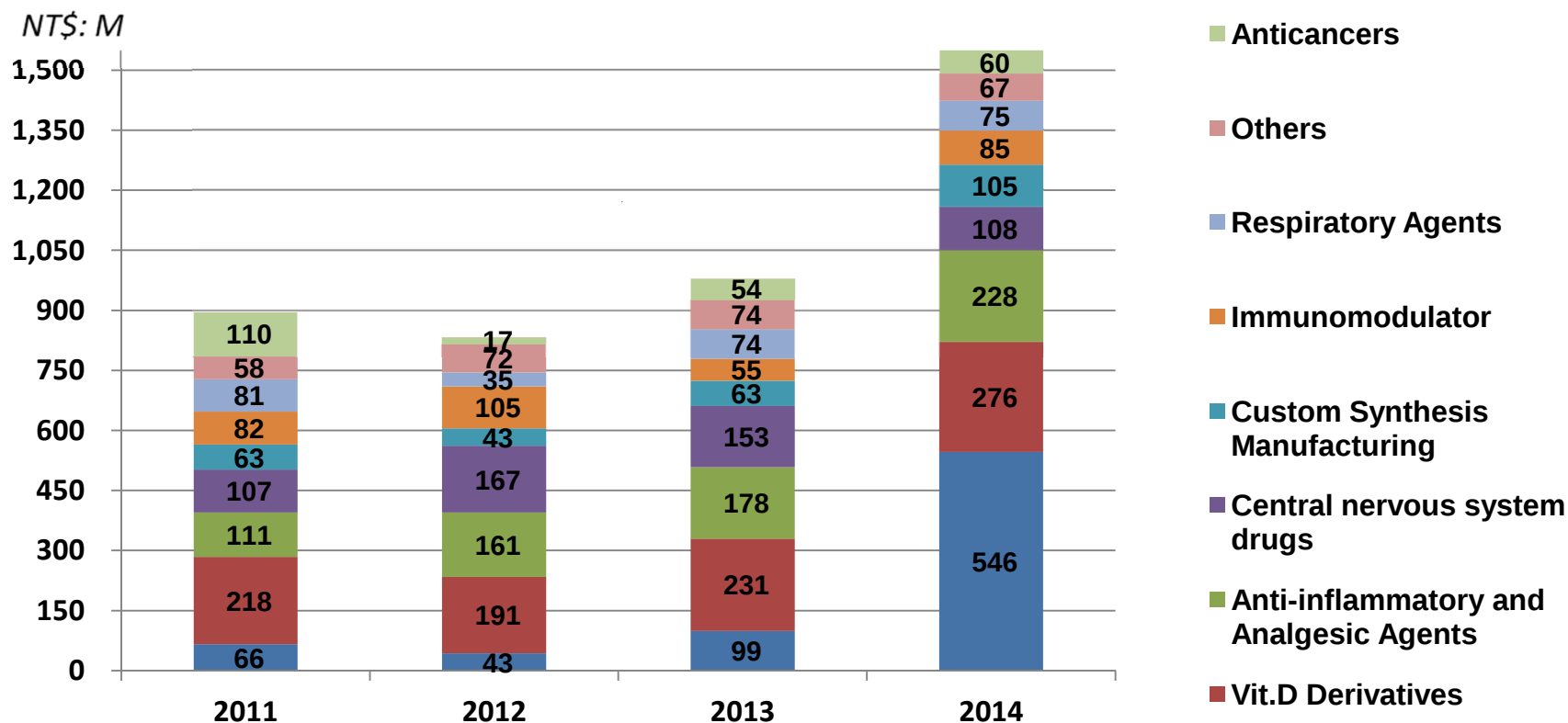


Efficiency in Transition- Company



Impact of New API Facility Implementation

- Cholesterol and Phosphate Binder products is the key contributor to revenue expansion of API in 2014



New Projects in Development

Developing products; 13 in total

- 3 Anticoagulant
- 4 Anticancers
- 2 CNS Agents
- 1 Cholestrol binder
- 1 Hormonals
- 2 UV filters

Ongoing customized R&D Projects; 12 in total

- 11 New drug
(1 NDA, 1 Phase III, 2 Phase II, 3 Phase I, 3 Pre-IND)
- 2 Generic



Exploring New Platform and EM

- **Protein APIs and ADCs Market**

- Founded EirGenix Inc., a protein drug CMO, in 2012.
- Collaborated with Eirgenix and Tube Pharma, an Austrian company for ADC, antibody-conjugated complex pipelines

- **Supply Chain in China**

- Expected to have contribution from 2017
- Founded an API manufacturer, Shiner Pharmaceuticals, in China. Expected to have contribution in 2016H2.

- **New Drug Development**

- A fully owned subsidiary, Formosa Pharma., is cooperating with NTUH and TMU conducting a phase I clinical trial for cancer patient treatment



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Sales Review



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Business Outlook

UV Blocker

Maintain cash flow positive

- **B/S**

Cost: NT\$ 93M

Booked value as of NT\$ 45M at the end of Feb, 2015

Annual appreciation at NT\$ 9M

- **Performance**

Sales drop significantly since 2012 till now

Maintained cash flow positive for the product line in 2014

- **Outlook**

Limited expenses in marketing

Maintain cash flow positive for the line

Transfer facility and manpower for intermediates and API manufacturing



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Sales Review

API

APIs to be launched

(US mil)

Product	Therapeutic Use	US	EU	JP	TW	Worldwide Sales 2013 Q4 – 2014 Q3
Colesevelam HCl	Antihyperlipidemic	2015Q2	NA	NA	NA	663
Sevelamer Carbonate	Antihyperphosphatemic	2015Q3	2015Q1	NA	2015Q4	1,616
Sevelamer HCl	Antihyperphosphatemic	2015Q3	NA	NA	2012Q3	
Gadoterate Meglumine	Diagnostic Aid (MRI Contrast Agent)	2018Q1	2016Q4	NA	NA	194
Linezolid	Antibiotic	2015Q2	2016Q1	2015Q2 (injection) 2015Q2 (tablet)	NA	1,303
Maxacalcitol	Antihyperparathyroid	NA	NA	2015Q3	NA	165
Paricalcitol	Antihyperparathyroid	Launched	Launched	NA	NA	297
Pazopanib	Antineoplastic	NA	NA	NA	2016Q1	666
Temozolomide	Antineoplastic	2015Q2	2016Q1	2016Q3	NA	829

Market Development

Japan

Customer : Nichi-iko, Sawai, Towa, Fuji Pharma, Meiji-Seika..etc.

Launch products (6) :

Gadodiamide, Tegafur, Gimeracil , Oteracil , Taltirelin and Linezolid

Registration products(6) :

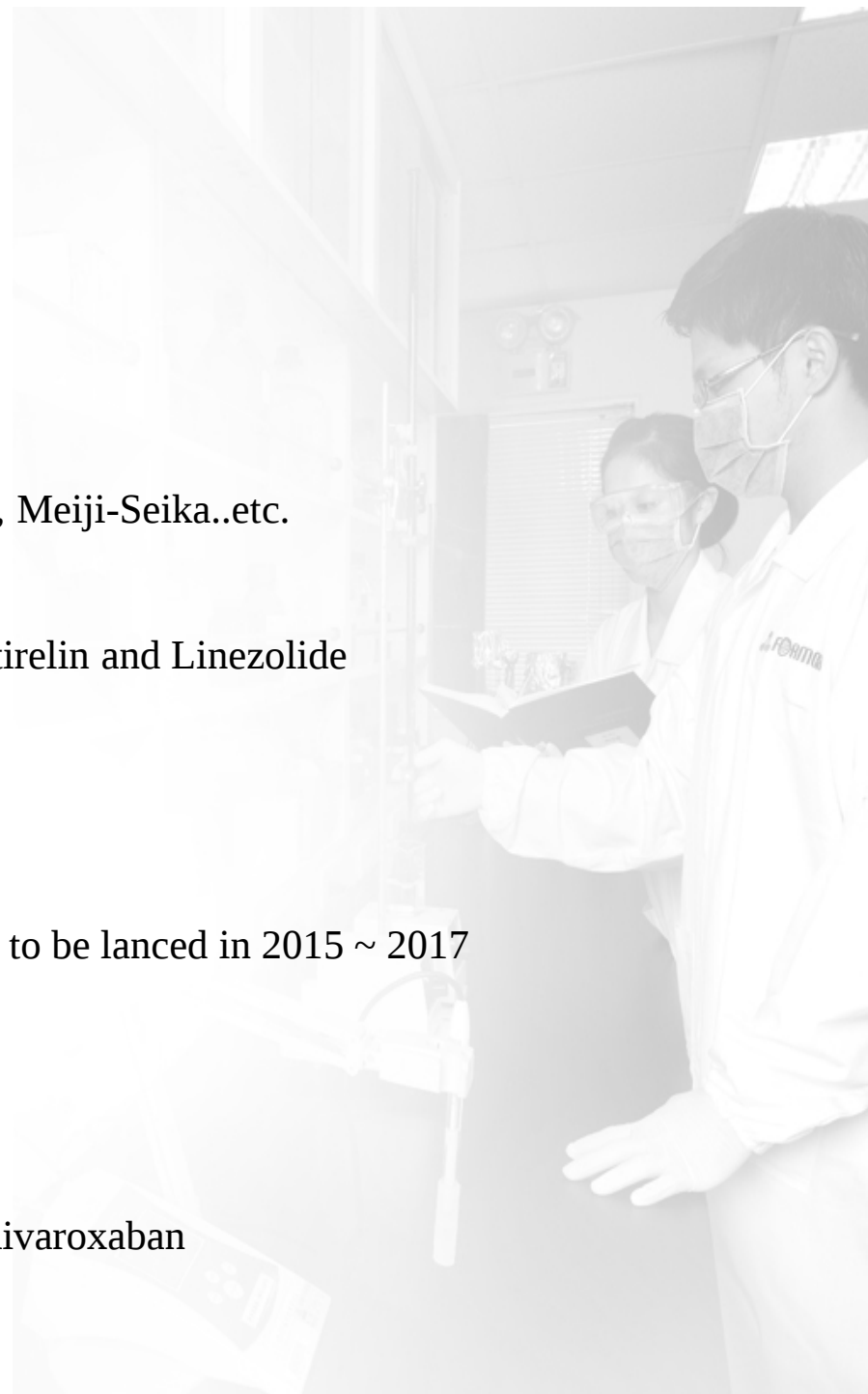
3 Vit. D Derivatives and 1 Anticancers

Formulation market for above products : 826 mil, to be lanced in 2015 ~ 2017

Market share for above products : 5~10%

Development products :

Sevelamer HCl, Levonogrestrol, Bazedoxifene , Rivaroxaban



Market Development

Korea

Customer : Hanmi , CKD (top 2 in KR)

Launch products (5) : Calcitriol, Alfacalcidol, MMF, Leflunomide, Benzonatate

Registration products(3) :

Orlistat - Formulation to be launched in 2015 Q2 , Annual formulation sales US 53 mil with more than 35% market share expected.

Calcipotriol - Formulation to be launched in 2015 Q2 , Annual formulation sales US 6.5 mil with more than 70% market share expected.

Balsalazide - Formulation to be launched in 2015 Q2 , Annual formulation sales US 3.7 mil with 100% market share expected.

Development products : Paricalcitol, Dasatinib, Sevelamer Carbonate, Linezolid, Taltirelin

Market Development

Brazil

Our customers included the Top 5 in Brazil which are EMS, Sanofi, ACHE, Brainfarma, Eurofarma

Four products in the market : Calcitriol, Alfacalcidol, MMF, Sevelamer HCl

Sevelamer HCl - Annual formulation sales US 110 mil, Our customer just now granted approval of marketing authorization from ANVISA with 5 years bid, expect to start the shipments on Jul, 2015.

Three products to be launched :

Orlistat - Formulation to be launched in 2017, Annual formulation sales US 132 mil with more than 15% market share expected.

Leflunomide - Formulation to be launched in 2017, Annual formulation sales US 26 mil with more than 20% market share expected.

Temozolimide - Formulation to be launched in 2017, Annual formulation sales US 295 mil with more than 25% market share expected.

Products under development : Imatinib, Pazopanib

Market Development

Turkey

In year 2012, Turkey has ranked 6th pharmaceutical market in EU and 16th in the world. The pharmaceutical market is up to US 8,000 mil recently, Generic market share has taken 37%. The market is optimistically growing, due to the increased local population, and the health welfare policy and support from Turkey government.

Launched Product

Sevelamer HCl –Supply steadily

Under Registration

Sevelamer Carbonate – Formulation to be launched in 2016, Annual formulation sales US 4 mil with 40% market share expected.

Temozolomide- Formulation to be launched in 2016, Annual formulation sales US 9.5 mil with 40% market share expected.

Paricalcitol – Formulation to be launched in 2017, with 35% market share expected.

Gadodiamide– Formulation to be launched in 2017, with 30% market share expected.



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Q & A



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附件

2015/1 營收

2014Q3 財報 & 營運分析

2015/1 ~ 2 sales

Unit: NTD (mil)	2014/1~2		2015/1~2		YoY
Category	Sales	%	Sales	%	
UV filters	157.4	45%	56.3	20%	-64.20%
API	194.4	55%	218.8	80%	12.50%
Total	351.8	100%	275.1	100%	-21.80%

Top 5 of API products (90.4% sales in total)

- | | |
|-------------------------------------|-------------------------|
| 1. Cholesterol and Phosphate Binder | NT\$ 94.3M , YoY +82% |
| 2. Respiratory Agents | NT\$ 40.8M , YoY +297% |
| 3. Vit. D Derivatives | NT\$ 31.5M , YoY -19% |
| 4. CNS Agent | NT\$ 16.4M , YoY +200% |
| 5. Antibiotics | NT\$ 14.9M , YoY +1355% |

Consolidated Income Statement

NT\$ MM, except EPS	2014 Q1	2014 Q2	2014 Q3
Total operating revenue	609	786	576
Gross profit	147	201	212
Gross margin	24%	26%	37%
Operating expenses	98	109	115
Operating income	49	92	97
Operating margin	8%	12%	17%
Non-operating income	18	-21	10
Net Income after Tax	56	59	89
Net Income	11%	9%	18%
Income before taxes	9%	8%	15%
EPS After Tax	0.66	0.70	1.06

此表依會計師審計報告

Consolidated Income Statement

NT\$ MM, except EPS	Up to 2014 Q3	2013	Up to 2013 Q3
Total operating revenue	1,971	2,474	1,734
Gross profit	600	339	181
Gross margin	28%	14%	11%
Operating expenses	322	414	305
Operating income	238	-75	-124
Operating margin	12%	-3%	-7%
Non-operating income	7	17	2
Net Income after Tax	204	-69	-117
Net Income	12%	-2%	-7%
Income before taxes	10%	-3%	-7%
EPS After Tax	2.42	-0.97	-1.72

此表依會計師審計報告

Consolidated Balance Sheet

NT\$ MM	Sep 2014		Jun 2014		Sep 2013	
Cash & cash equivalents	289	6%	207	4%	622	13%
Receivable-net	653	12%	778	15%	727	15%
Inventories	931	18%	828	17%	672	14%
Long-term investments	348	7%	281	6%	156	3%
Total fixed assets	2,446	47%	2,399	47%	2,132	43%
Total other assets	582	10%	553	11%	574	12%
Total assets	5,249	100%	5,046	100%	4,882	100%
Total current liabilities	1,260	24%	1,661	33%	1,594	33%
Long-term liabilities	508	10%	561	11%	739	15%
Other liabilities	649	12%	166	3%	255	5%
Total liabilities	2,417	46%	2,388	47%	2,588	53%
Total shareholders' equity	2,832	54%	2,658	53%	2,294	47%
The Net Asset Value of Each Share	33.56		31.49		28.45	

此表依會計師審計報告

Consolidated Cash Flow Summary

NT\$ MM	2014 Q3	Up to 2014 Q3	2013
Cash and cash equivalents at beginning of period	207	413	255
Cash flows from operating activities	132	190	32
Additions to property, plant and equipment	(122)	(372)	(549)
Cash flows from investing activities	(13)	(28)	(124)
Cash flows from financing activities	85	86	799
Cash and cash equivalents at end of period	289	289	413

此表依會計師審計報告