



台耀化學股份有限公司



TWSE 4746

September 27, 2013

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Content

- ◆ **Brief Introduction of Company**
- ◆ **Business Review and Analysis**
- ◆ **Sales Review**





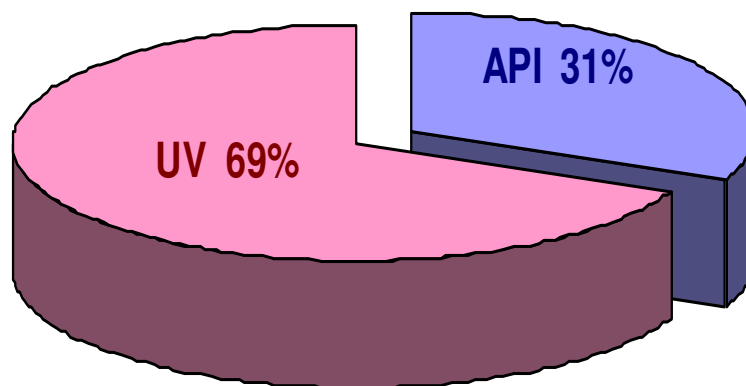
- Date of Establishment : Dec. 29, 1995
- Capital: NTD 806 Mil
- Staff : 477 (Sep. 2013)
- Area: 43,416 M²
- Major products: UV filters (among top 3 producers)
APIs (world-wide distribution; 34 active [US DMFs](#))
Custom synthesis: 10 projects



No. 36 Hoping, Louchu County, Taoyuan 33842, Taiwan R.O.C.

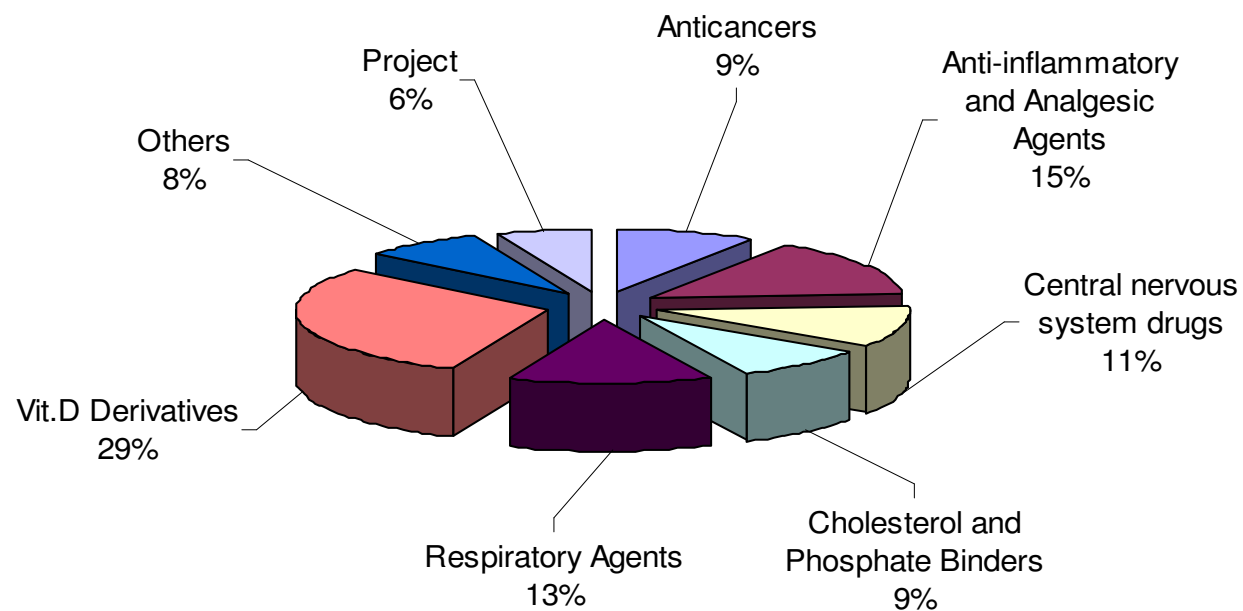
Sales by Products

2013 1st Half Year Sales



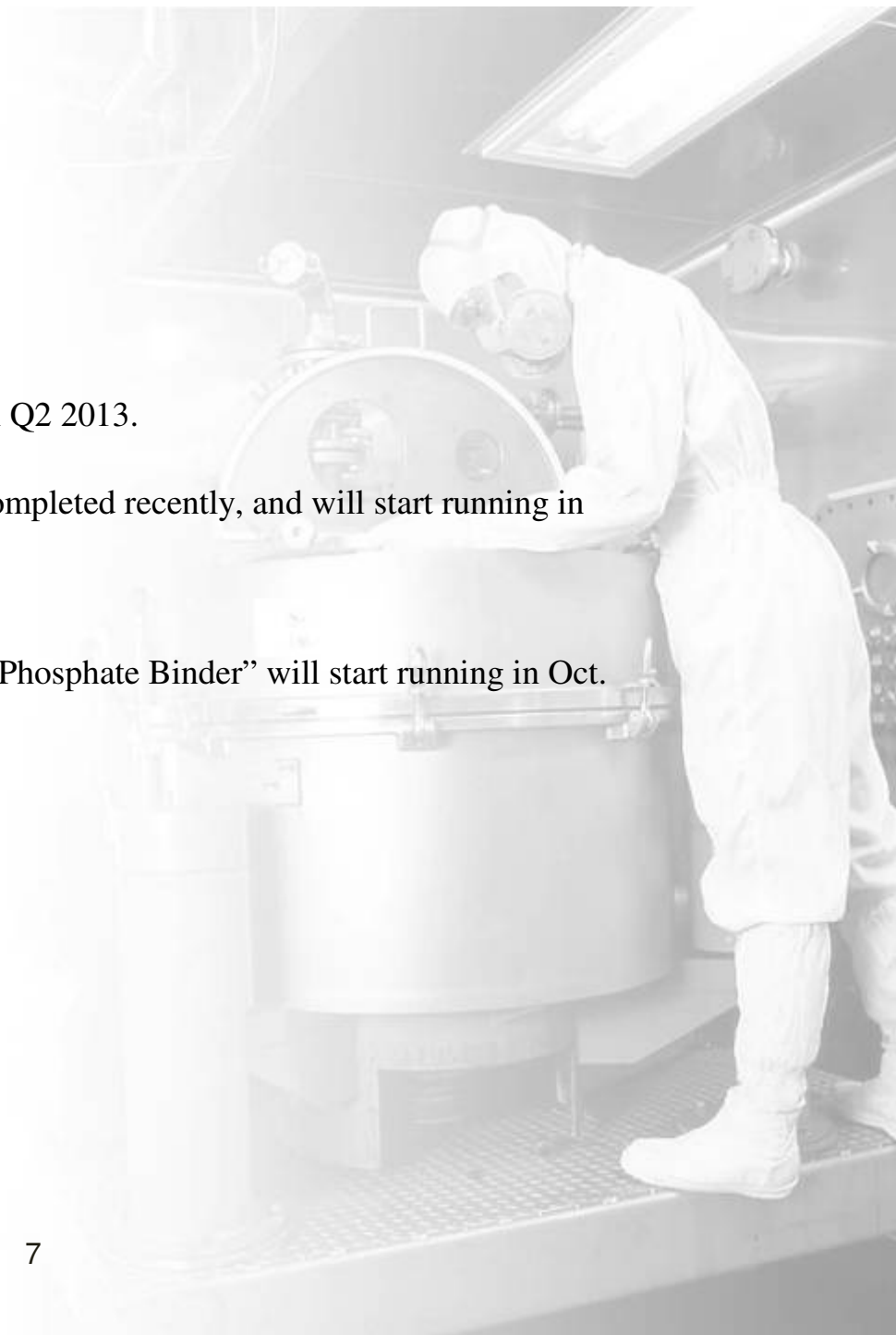
**Active Pharmaceutical Ingredients
Sales by Products**

- 2013 1H API Sales**



Business Status Update - 1

- A new general API plant was started running in Q2 2013.
- Water treatment facilities expansion has been completed recently, and will start running in Oct.
- A new plant for production of “Cholesterol and Phosphate Binder” will start running in Oct.



Business Status Update - 2

UV filters:

- Sales revenue increased at least 4% continuously for three years from 2009 to 2012 .
- The summer time came late and went early in North American and European countries this year cause the major consumption goes down.
- The tendency of global demand is still optimistic.
- DSM brand, Parsol, bring advantage of sales.
- cGMP regulation requirement is getting stricter day by day. Formosa is cGMP compliance API company who will survive when the new competition barrier form.

Business Status Update - 3

APIs:

Sales revenue was affected by capacity crunch in 1H which is being gradually recovered with the move of certain production to our new plant.

- Up to date, Formosa support 18 of PIV filers and 2 of 505(b)(2) filers with 10 of non-infringing APIs.
- DMF status update :
 - 34 USDMF
 - 4 CEP
 - 9 EUDMF
 - 6 JMF
 - 28 TDMF
 - 5 CNDMF
- The customers in Brazil and Turkey launched Sevelamer HCl formulation recently. The demand is increasing and will be filled by our new plant production in Oct.

Sales Review - 1

US and EU generic market

- Calcipotriol – Sign a long term supply agreement with a well-known multinational pharmaceutical company in Q3 for European market.
- Colesevelam – Supported 5 ANDA filings in the US, including two out of four PIV filers. The two have got market exclusivity for 3-6 months.
- Orlistat – Expect to get approval from EU authorities by end of the year.
- Sevelamer hydrochloride – The formulation using our API was launched in Brazil and Turkey in Q3.

Sales Review - 2

JP generic market

- TS1 – The generic formulation using our 3 APIs (Tegafur 、Gimeracil and Oteracil) has been approved by PMDA in Aug.
- Maxacalcitol –JMF will be submitted by end of the year. Expect to be commercialized in 2015.

New drug project

- Supported 10 new drug projects as API supplier.
 - 4 Pre-IND
 - 2 Phase I
 - 2 Phase II
 - 1 Phase III
 - 1 NDA

China generic market

- More than 30 customers have been developed with 14 APIs including 4 Vit. D compounds and 2 “cholesterol and phosphate binder” which are being registered with SFDA.

JV or Investment projects

- Formosa Pham (台新藥)- MPTOE028, Good progress, IND to be filed by end of this year
(HDAC inhibitor as anticancer) ◦
- TaiRx(台睿) – New drug TRX-818 、TRX-606 and EFP-306 , TRX-818 as anti-cancer
Novartis is interested in investment in TRX-818 as anti-cancer ;
to be completed animal testing in 2014 and apply clinical trials
- Glory Biotech(得榮) – Joint development and production of fermented bulk drugs, Initial
public offering last year.
- Sen-Hwa Biotech (生華) – committed 5% share holding; strategic partner in fermentation
API production

Thank you



Additional Information

DMF status

Item	# of DMF
Anti-cancers	5
Anti-inflammatory and Analgesic Agents	2
Central nervous system drugs	2
Cholesterol and Phosphate Binders	4
Immunomodulator	4
Respiratory Agents	2
Steroids	2
Vit. D Derivatives	8
Anti-Obesity	1
UV Filters	1
Others	3
<u>Total</u>	<u>34</u>



P 4 API

預估上市時程	產品 (API)	製劑	專利到期日	ANDA filing date	US藥品市值 (US\$ mil)*	U.S. Consumption	全球藥品市值 (US\$ mil)*	W.W. Consumption	上市或預計上市時程	狀態
2006 Oct	Colestipol	tablet	13-Feb-13	23-Aug-05	33.1	77,751kg	35.6	97,479.8kg	24-Oct-06	上市; 1 P4 out of 1 include FTF
2008 Q2	Calcipotriol	solution	9-Jun-15	2006/5/19 2008/11	396	5.1kg	849.5	42.1kg	2008/5/6 2011/3/24	上市; 2 P4 out of 5 include FTF
2015 Q2	Orlistat	capsule; 60mg, 120mg	6-Jul-18	2012/6 2012/6	49	4,926.9kg	442.9	70,215.9kg	30-Jun-15	2 P4 out of 2 include FTF
2014 Q1	Doxercalciferol	soft gel capsule	11-Feb-14	12-Feb-10	47.3	0.1kg	47.3	0.1kg	11-Feb-14	1 P4 out of 5 include FTF
2014 Q2	Paricalcitol	soft gel capsule	2014/6/24 2016/1/13	2010/7 2012/6 2012/10	110.5	0kg	149.5	0kg	24-Jun-14	3 P4 out of 6
2015 Q1	Paricalcitol	injectable	2014/6/24 2016/1/13 2018/10/8	2008/11/28 2011/4 2012/1 2012/2 2013/7	196.6	.1kg	269.7	.1kg	2015/3 2016/1/13	3 P4 out of 5 include FTF 2 505(b)(2) NDA out of 2
2014 Q1	Sevelamer carbonate	powder, tablet	16-Sep-14	2011/3/22 2012/7/15	935.8	322,125.3 kg	1,222.30	536,120.2 kg	2014/9/16 2014/3/16	2 P4 out of 6
2014 Q3	Sevelamer HCl	tablet		7-Apr-11					16-Sep-14	1 P4 out of 5
2015 Q2	Ixabepilone	powder	26-Nov-18	16-Apr-12	66.2	1.1kg	67.8	1.2kg	16-Apr-15	1 P4 out of 1 include FTF
2015 Q1	Colesevelam	powder, tablet	2-Jun-15	2009/7/1 2010/7	495.4	250,277.2 kg	503.7	256,515.7 kg	2015/1/2 2015/4/2	2 P4 out of 4 include FTF
* IMS ww year end MAR 2013					2329.9		3,588.3			total 18 PIV and 2 505(b)2



Consolidated Income Statement

NT\$MM, except EPS	Q1 2013 (Audited)	Q1 2013 (Audited)
Total operating revenue	238	778
Gross profit	(95)	112
Gross margin	18%	14%
Operating expenses	85	106
Operating income	(180)	6
Operating margin	-76%	1%
Non-operating income	10	1
Net Income after Tax	(164)	2
Net Income	-72%	1%
Income before taxes	-69%	-
EPS After Tax	(2.45)	0.03

Consolidated Balance Sheet

NT\$MM	2013/03/31 (Audited)		2013/06/30 (Audited)	
Cash & cash equivalents	509	13%	235	5%
Receivable-net	266	7%	755	17%
Inventories	726	18%	692	16%
Long-term investments	70	2%	158	3%
Total fixed assets	1,867	47%	1,977	45%
Total other assets	553	13%	598	14%
Total assets	3,991	100%	4,415	100%
Total current liabilities	1,547	39%	1,702	39%
Long-term liabilities	447	11%	713	16%
Other liabilities	489	12%	490	11%
Total liabilities	2,483	62%	2,905	66%
Total shareholders' equity	1,508	38%	1,510	34%

Consolidated Cash Flow Summary

NT\$MM	Q1 2013 (Audited)	Q2 2013 (Audited)
Cash and cash equivalents at beginning of period	255	509
Cash flows from operating activities	174	(373)
Additions to property, plant and equipment	(102)	(181)
Cash flows from investing activities	(42)	(50)
Cash flows from financing activities	224	330
Cash and cash equivalents at end of period	509	235