

Mayne Pharma Group Limited

Business update

Today's presenters



Scott Richards

CEO

Managing Director

- Appointed Feb 2012
- 24 years global pharma industry experience
- Prior experience:
 - President, European Operations and Global Hospital Business, Intas Pharmaceuticals
 - Executive Vice President, Global Hospital Business, Actavis Group
 - President, Global Commercial Operations, Mayne Pharma
 - President, Europe/Middle East/Africa, Mayne Pharma
 - VP/GM, Faulding Pharmaceuticals, ANZ
 - VP, Purepac Pharmaceutical Co (US)



Mark Cansdale

CFO

Company Secretary

- Appointed Dec 2010
- 20+ years experience
- Prior experience:
 - CFO and Company Secretary at ASX-listed McMillan Shakespeare
 - CFO and Company Secretary at Vision Systems
 - M&A, corporate strategy, tax, financial planning and analysis, risk management, treasury and investor relations

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Executive summary

- Mayne Pharma Group Limited (“**Mayne**”) is an ASX-listed specialty pharmaceutical company
 - has its origins as the drug delivery technology arm of FH Faulding & Co
- In-market global sales today of developed products of ~US\$500 million¹ pa
- Three core growth drivers :

Exploitation of world-class oral drug delivery platform

Proprietary products—e.g. SUBACAP®
Generic targets—US market focus

Exploitation of Mayne brand and product portfolio

Domestic own brand portfolio
International out-licensing of product portfolio

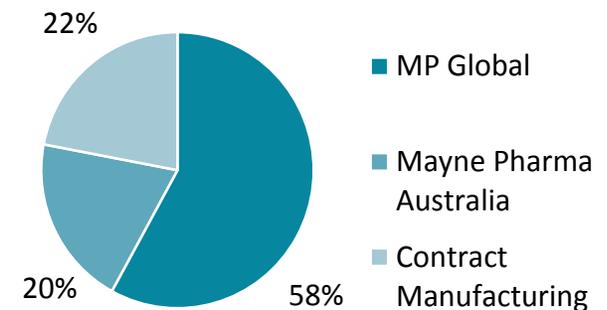
Partnering services to global pharma

Collaborative development with global pharma
Contract manufacturing

- Mayne operates from an owned 32 acre facility located in Salisbury (Adelaide), South Australia (FDA, TGA, EMEA approved), where it undertakes drug development and manufacturing supported by approximately 150 staff

Sales revenue by business (excl. R&D income)

FY 2011



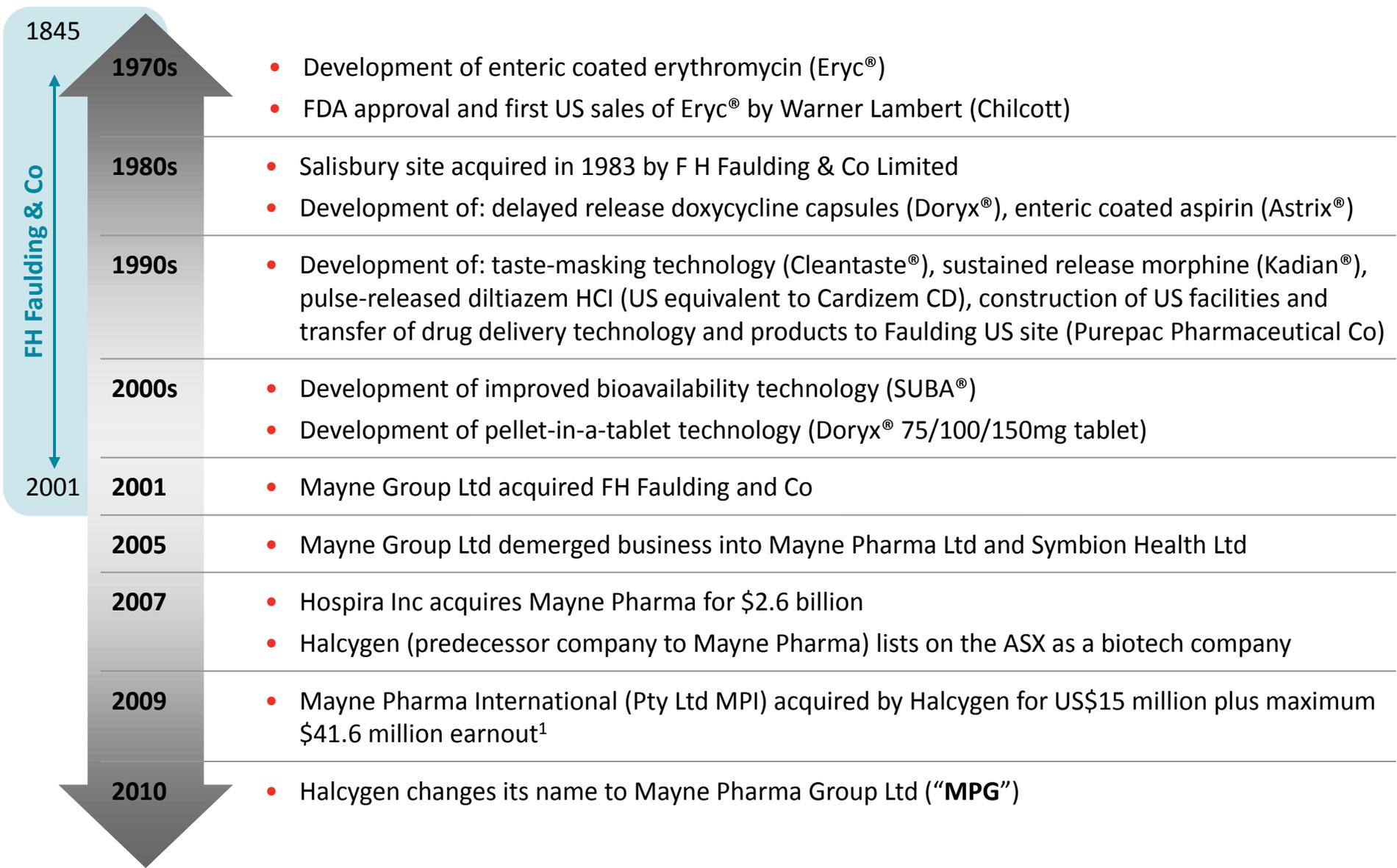
Summary financials

A\$m, JunYE	FY11	HY12
Sales revenue	47.0	26.8
EBITDA ²	9.2	6.3
EBITDA margin % ²	19.6	23.5

1. IMS Health (ex-wholesale) 2011

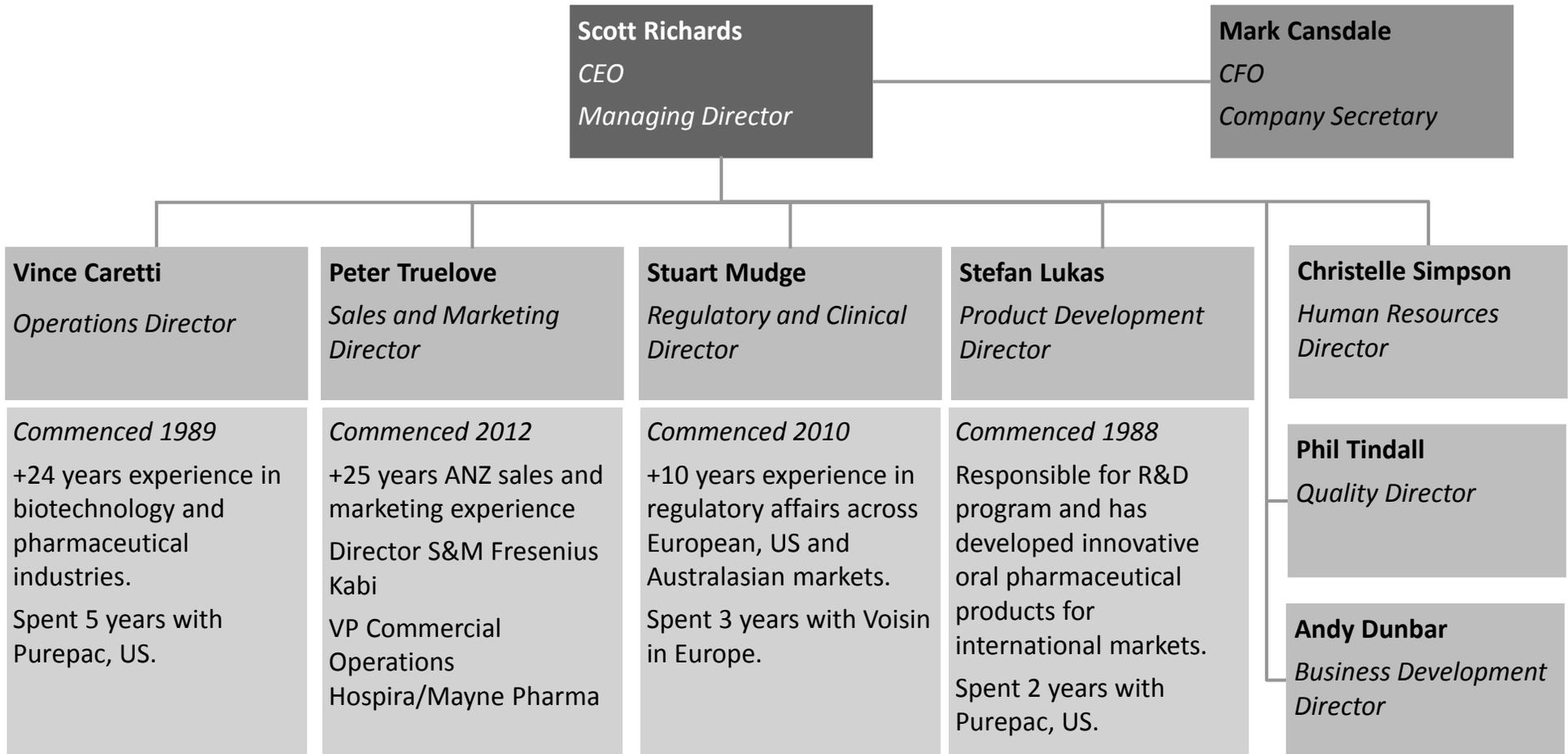
2. Underlying EBITDA. Refer to notes on Financial Summary page

Evolution of Mayne Pharma



1. Earn out liability component payable until October 2015. Refer to notes on Financial Summary page.

Expanded/enhanced management capabilities to drive business development activities



- Employs over 150 people with 20 highly skilled and technical staff dedicated to the development of new products

Develop and manufacture proprietary and generic products using oral drug delivery technologies:

	For out-licence <i>MP Global</i>	For domestic sale <i>Mayne Pharma Australia</i>	Research and development	Contract manufacture
FY11 Sales Revenue	A\$27m	A\$9m	na	A\$11m
Key products	<ul style="list-style-type: none"> • Doryx[®] • Kadian[®]/Kapanol[®] • Eryc[®] • Astrix[®] 	<ul style="list-style-type: none"> • Doryx[®] • Astrix[®] • Eryc[®] • Magnoplasm[®] 	<ul style="list-style-type: none"> • Development of SUBACAP[®] • Development of generic and proprietary complex modified release products 	<ul style="list-style-type: none"> • Liquid • Cream
Key territories	<ul style="list-style-type: none"> • US • Australia • Canada • Korea • Japan • European Union 	<ul style="list-style-type: none"> • Australia 		<ul style="list-style-type: none"> • Australia

MP Global

- Out-licensing of proprietary pharmaceuticals globally
- Long standing customer relationships with leading international pharmaceutical organisations such as Warner Chilcott, GlaxoSmithKline, Pfizer, Abbott Laboratories
- New formulations of proprietary products under development to expand the product offering
- Existing product portfolio to be rolled-out into more markets (only distribute a small portion of the existing portfolio in 10 countries today)
- MP Global (excluding Doryx®) growing ~18% pa driven by Astrix®, Kadian® and Eryc®

Mayne Pharma Australia

- Manufacture, distribution and marketing of proprietary pharmaceuticals in Australia
- Existing portfolio includes prescription and over-the-counter products
- New pricing program implemented for key products in 2H FY12
- Transferring manufacture of ~300 million Astrix® and Mayne Pharma branded aspirin tablets in-house in 2012
- In-licensing new products not currently available in Australia, focusing on generic injectable and niche proprietary segments
- Create scale in the Australian business to further invest in own sales and marketing capability
- Mayne Pharma Australia growing ~6% pa

R&D review

- 90 day R&D review examined the top 400 US molecules by sales
- Primary selection criteria:
 - time to market (TTM)
 - leverage MPG’s skill base and facilities
 - minimal clinical/legal/regulatory risk and cost
 - attractive present and future market
 - US target market
- Identified a product candidate pool representing US\$11 billion¹ in annual sales
- Two projects selected and development activity has commenced
 - current annual sales: US\$1.2 billion¹
 - TTM: ~3–5 years
 - regulatory pathway: AB-rated ANDA²
 - collaborative program with global drug delivery company

R&D capability

- Three of the most successful products developed by MPG were responsible for ~\$2.5 billion³ in in-market US sales over the last 5 years
- All three are applications of modified release technology

Kapanol/Kadian

- Kadian[®] (sustained release oral morphine) was the first Australian product to file and gain a new drug application in the US
- Sales ~US\$265 million¹

Doryx

- Doryx[®] capsules were launched in 1985 and reformulated into tablets in 2005
- Sales ~US\$260 million¹

Diltiazem hydrochloride ER

- Generic equivalent to Cardizem ER, one of the most complex modified release oral products
- Sales ~US\$60 million¹

1 IMS Health (ex-wholesale US sales (MAT) Dec 2011

2 Abbreviated new drug application

3 IMS Health (ex-wholesale US sales)

Mayne provides a range of services to third parties:

- The Company focuses on assisting partners in the areas of:
 - oral drug delivery systems
 - pellet products and microencapsulation
 - liquids and cream
- Sales revenue from contract liquids and creams up ~9% in FY12

Contract services

- Third party product development and contract manufacturing

Manufacturing

- Commercial contract manufacturing of third party products

Pharmaceutical partners :



Overview of facilities

Mayne's 32 acre facility at Salisbury, South Australia has 12,000m² of manufacturing space with TGA, EMEA and FDA approval

- annual production capacity of:
 - c.2,500 million capsules/tablets
 - 100 tonnes of bulk product
 - 16 million units of liquids and creams



Play to strengths while diversifying earnings base in complementary products, technologies and market segments

Leverage off MP brand globally

- Re-establish global visibility of the Mayne Pharma brand
- Targeted in-licensing of niche generic and specialty products for Australian market

Optimise revenue base

- Drive growth of existing portfolio through targeted out-licensing and improved domestic sales and marketing activity
- Create scale in MP Australia to invest in own S&M capability
- Retain and grow contract manufacturing client base

SUBACAP[®] commercialisation

- Optimise potential in superficial and systemic infection markets
- Execute regulatory strategies to minimise time to market
- Broaden IP portfolio and develop value add line extensions

Expand R&D program

- Create a multi-project risk-balanced portfolio
- Prioritise on basis of time to market, capability alignment and market attractiveness
- US market bias, initial generic channel bias

Diversify and grow

- Aggressively pursue product and enterprise acquisitions
- Immediately accretive and mature assets with strong growth potential
- US bias for international investments

Description of technologies

Controlled release delivery systems	Sustained release	Steady levels of drug concentrations over 12–24 hours following a single dose
	Modified release	Immediate release of a small portion of drug followed by the delayed release of the balance
	Pulsed release	Pulse release of drug over 12–24 hours following a single dose
	Delayed release	Targets the drug to a specific site in intestinal tract, particularly avoiding release in the stomach
SUBA®	Improved bioavailability	Particularly for poorly soluble drugs (SUBA®)
Cleantaste®	Taste masked	Allows drugs to be more palatable and easier to swallow (Cleantaste®)

Benefits

Decreased dosing frequency and increased compliance
 Reduced peak-to-trough ratio of drug in systemic circulation
 Reduced rate of rise of drug concentration in blood
 Sustained and consistent blood levels within the therapeutic window

Reduced variability b/w patients, reduced side effects

Reduced side effects, improved compliance & ease of use

Overview of SUBACAP[®]

- Significantly improved formulation of itraconazole (anti-fungal product) based on SUBA[®] technology (improved bioavailability)
- Conventional itraconazole hampered by erratic/unpredictable clinical response (poorly controlled absorption) and safety issues
- SUBACAP[®] formulation provides for significantly less variable drug absorption (fed/fasted state)
- Less intra/inter patient variability, more predictable clinical response and potential for reduced toxicity
- Itraconazole is one of the broadest spectrum antifungal drugs on the market and can be used to treat both:
 - superficial infections—onychomycosis (nail infection)
 - systemic infections—histoplasmosis, aspergillosis, blastomycosis and candidiasis
- Potential opportunity to create two brands

Market potential

Targeting the global itraconazole market

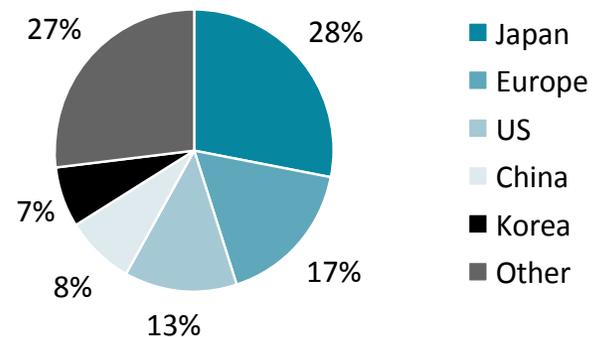
- >US\$500 million ex wholesale sales in 2011 and stable¹

Broader systemic antifungal application

- US systemic anti-fungal market (excluding itraconazole) valued at US\$650 million in 2011¹

Itraconazole sales by country¹

2011



1. Source: IMS Health

Europe

- On 20 June 2012, following six months of consultation with Mayne Pharma, the UK Medicines and Healthcare Regulatory Agency (“MHRA”) reversed its previous decision on SUBACAP[®] and advised that:
 - the SUBACAP[®] Marketing Authorisation Application (MAA) is approvable in the UK
 - MHRA-proposed label is very favourable and clearly differentiates SUBACAP[®] versus the reference product
 - Mayne Pharma can reactivate the Decentralised Procedure to seek approval in Germany, Spain and Sweden. Anticipate receiving approval within next 6–12 months (~US\$35 million pa¹)
 - seek 2nd round of approvals in select other European countries such as Italy, Belgium, Netherlands, Greece, Portugal (~US\$50 million pa¹)

USA

- Positive Phase II onychomycosis study completed
- Currently refining the proposed US regulatory pathway
 - seeking agreement from US FDA for the design of the Phase III clinical trial in onychomycosis
 - requesting a meeting with the FDA to discuss the argument presented to the MHRA; potential to fast track without Phase III study

Australia

- Seeking pre-submission meeting with Therapeutic Goods Administration (TGA) in 2012 in anticipation of applying for marketing approval of SUBACAP[®] in 2013

Rest of world

- ROW ~US\$370 million¹ annual itraconazole sales
- Japan and Korea (> US\$180 million pa¹) are priority markets

1. Source: IMS Health (ex-wholesale)

Doryx patent—situation overview

- Doryx[®] is a doxycycline formulation containing enteric - coated delayed release pellets designed to minimise nausea whilst still providing therapeutic blood levels of doxycycline
- In May 2012, the US District Court upheld the validity of the US patent covering the Doryx[®] 150mg product
- The Court also determined that the proposed generic versions of the Doryx[®] 150mg product to be launched by Mylan and Impax did not infringe this patent
- As a result, Mylan entered the market in May 2012 with a single-scored generic version of the Doryx[®] dual-scored 150mg tablets
- Impax approval timing uncertain
- Dual-scored approval status unknown for Mylan and Impax



Update

- Doryx[®] appeal has been filed with the US Court of Appeals for the Federal Circuit
- US prescription volumes not following typical generic substitution curve
- Warner Chilcott maintaining full 75 person sales force on Doryx[®] product

“Doryx[®] (acne) could top our model and make our earnings conservative as generic erosion has been less-than-expected.”

Buckingham Research Group

Warner Chilcott report, 5 June 2012



Summary P&L

A\$m, JunYE, reported	FY11	HY12
Sales revenue ¹	47.0	26.8
EBITDA (underlying)	9.2	6.3
<i>EBITDA underlying margin %</i>	<i>19.6</i>	<i>23.5</i>
Adjustments ²	(1.3)	2.5
EBITDA (reported)	7.9	8.8
EBIT	0.0	6.0
NPAT	1.7	3.9
EPS (cps)	1.1	2.6

Summary balance sheet

A\$m	30 Jun 11	31 Dec 11
Cash	5.8	6.1
PP&E	21.5	22.2
Total Assets	53.7	55.4
Debt	(2.3)	Nil
Earn-out liabilities (book value) ³	(15.1)	(12.6)
Total Liabilities	(29.5)	(27.2)
Equity	24.2	28.2
Net (Debt) / Cash	3.5	6.1

Note:

- 1 Sales revenue includes sale of goods and royalties revenue
- 2 FY11 Adjustments relate to: \$1.0m restructure of the business to improve efficiencies and increase capacity utilisation, \$1.1m inventory provision associated with Doryx[®] product not yet approved and \$0.8m credit in results representing a reduction in the earn-out valuation due to change in assumptions. HY12 Adjustments relate to: \$3.1m credit due to a reduction in the earn-out valuation due to reduced payments forecast to Hospira for CY11 and \$0.6m termination payment to the former CEO
- 3 Mayne has recognised a liability to the former owners of MPI representing deferred consideration payable over the period to 31 October 2015. The earn-out liability has been determined based on contracted royalty rates payable on expected future cash flows earned on certain products in calendar years across different geographic markets. The cash flows, assumed discount rate and forecast exchange rates are reviewed every six months to ensure the most accurate fair value of the liability is reported. Movements in the liability from changes in these assumptions and forecasts are reported in the consolidated statement of comprehensive income

A\$m, JunYE, reported*	Expectation
Sales revenue	\$51–53 million
Sales revenue growth	~10% p.a.
Underlying operating earnings (EBITDA)	\$10–12 million
Cash (up \$5.5 million from 31 December 2011)	\$11.6 million
Debt	Nil

* Results are subject to completion of year-end accounting procedures and external audit

Milestones achieved

- SUBACAP® approvable in UK
- Debt paid down
- Appointment of Adelaide-based CEO and Sales and Marketing director
- Commencement of two new R&D projects
- Renegotiated major contract customer for a further 3 years
- Manufacture of aspirin tablets in-house

Milestone achieved

- ✓
- ✓
- ✓
- ✓
- ✓
- ✓

Future catalysts for value

- Regulatory approval of SUBACAP® in Europe and partner identification
- Optimal US regulatory pathway and partner identification for SUBACAP®
- Appointment of new international distribution partners for existing products
- Expand MP Australia portfolio with niche generic and specialty products
- Deliver on key milestones for broader R&D program
- Product and enterprise synergistic acquisitions

Expected timing

- FY13*
- FY13*
- Ongoing*
- Ongoing*
- Ongoing*
- Ongoing*

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