



Mayne Pharma Group Limited - Investor Day 1 May 2017





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#### **Non-IFRS** information

- Other than as indicated, the financial information contained in this document is directly extracted or calculated from the
  audited Financial Statements. Throughout this document some non-IFRS financial information is stated excluding certain
  specified expenses. Results excluding such expenses are considered by the Directors to provide a meaningful basis for
  comparison from period to period.
- Earnings before interest, tax, depreciation and amortisation (EBITDA) is considered by Directors to be a meaningful measure of the operating earnings and performance of the Group and that this information maybe useful for investors and is a non-IFRS term.
- The non-IFRS financial information has not been audited by the Group's auditors.

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#### **Glossary**

 A glossary of industry terminology is contained in the Mayne Pharma Annual Report which can be accessed at <u>www.maynepharma.com/investor-relations/results-reports</u> and product descriptions are detailed at <u>www.maynepharma.com/us-products</u> and <u>www.maynepharma.com/australian-products</u>.



## Agenda

1 Introduction	Scott Richards Chief Executive Officer
2 Generic Products Division	Stefan Cross Chief Commercial Officer
3 Specialty Brands Division	Craig Boyd EVP, Specialty Brands
4 Metrics Contract Services	John Ross President, Mayne Pharma USA
5 Global Operational Excellence	John Ross President, Mayne Pharma USA
6 Research & Development	Ilana Stancovski EVP, Chief Scientific Officer
7 Corporate & Business Development	Peter Paltoglou EVP, Chief Development Officer
8 Closing Remarks	Scott Richards Chief Executive Officer



## 1 Introduction

Scott Richards

# VISION

At Mayne Pharma we are focused on delivering a healthier tomorrow. We believe that everyone deserves medicines that are better, safer and more affordable. That's why our people are determined to create clever, innovative products and services for our changing world.



### **Business snapshot**

### Mayne Pharma's focus

Hard to develop and manufacture products that bring therapeutic value to patients and payers

High quality contract services and manufacturing to third parties

Underpinned by expertise in drug delivery technology

~A\$600m annualised 1H17 revenues

70+ marketed and 50+ pipeline products

Products sold in 10+ countries



Provides CDMO<sup>1</sup> services to 100+ clients

**750+** employees

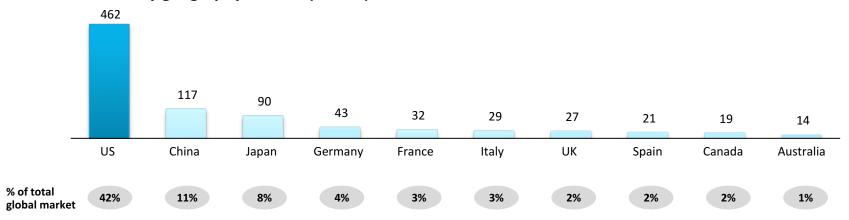
A\$90m+ invested in R&D since 2012

- Direct commercial presence
- Indirect presence through distribution partners for current and pipeline products

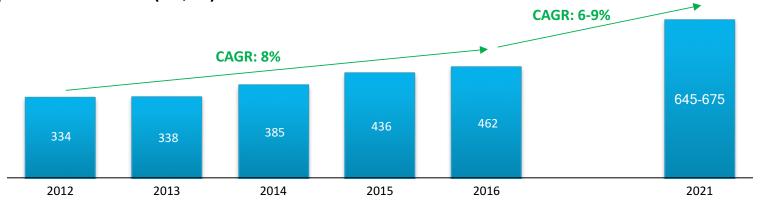


# US is the largest pharmaceutical market in the world...

### Global IMS sales by geography in 2016 (US\$bn)



### US pharma market size (US\$bn)

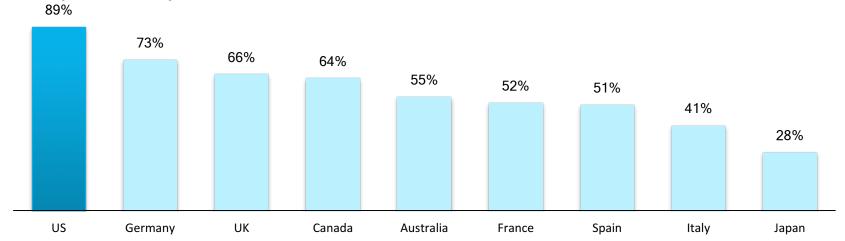


US market represents 42% of global pharmaceutical sales and expected to grow 6-9% p.a. over the next 5 years



## ...with the greatest generic penetration rate

### **Generic penetration by volume**



Source: Study report for the European Generic Medicines Association and public presentations.

### US generic pharma market size (US\$bn)







## Our transformation over the last 5 years...









marketed in the US



X

A\$2-3m spent on maintenance capex



A\$4.0m R&D spend



750

750+ employees



A\$100m+ spent on expansion capex

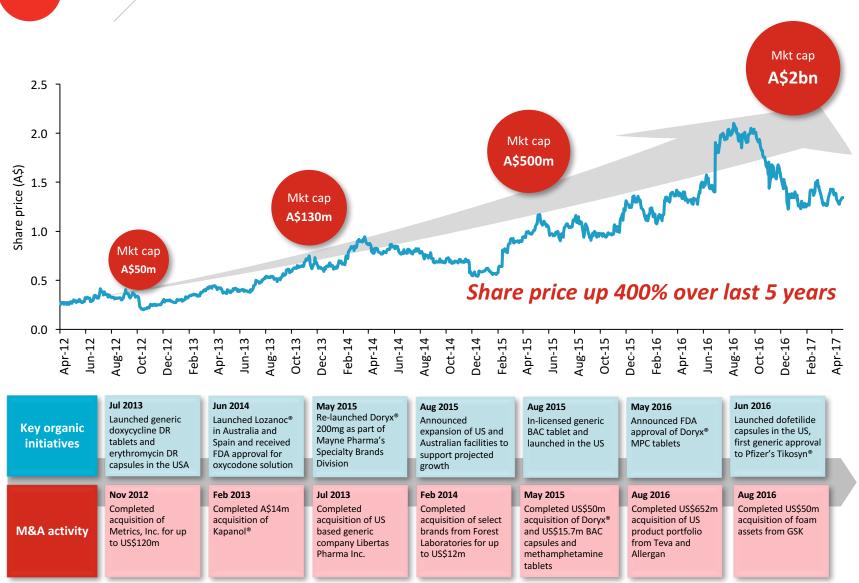


~A\$30m R&D spend

Mayne Pharma in 2017



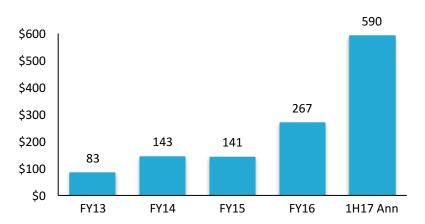
### ... has delivered value for shareholders...





## ...and outstanding financial performance

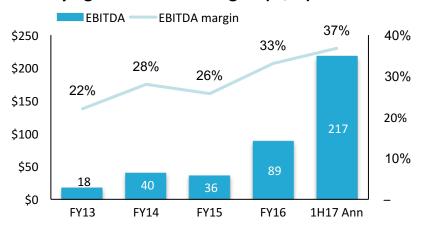
### Revenue (A\$m)



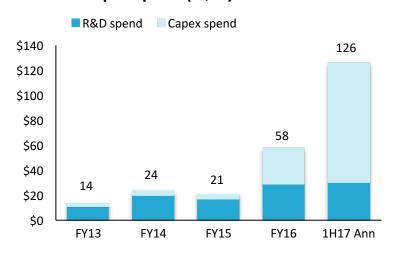
### Adjusted EPS<sup>2</sup> (cents per share)



### Underlying EBITDA<sup>1</sup> and margins (A\$m)



### R&D and capex spend (A\$m)



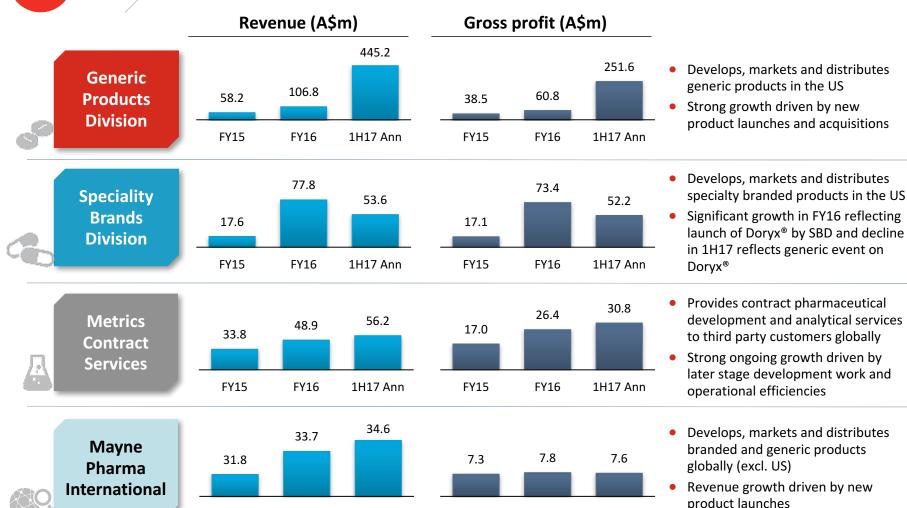
<sup>1.</sup> Refer to results announcements for underlying adjustments to EBITDA.

<sup>2.</sup> Adjusted EPS based on underlying NPAT excluding acquired amortisation.

Note: 1H17 results annualised for ease of comparison; not to be used as guidance.



### Strong performance across the business



FY15

FY16

1H17 Ann

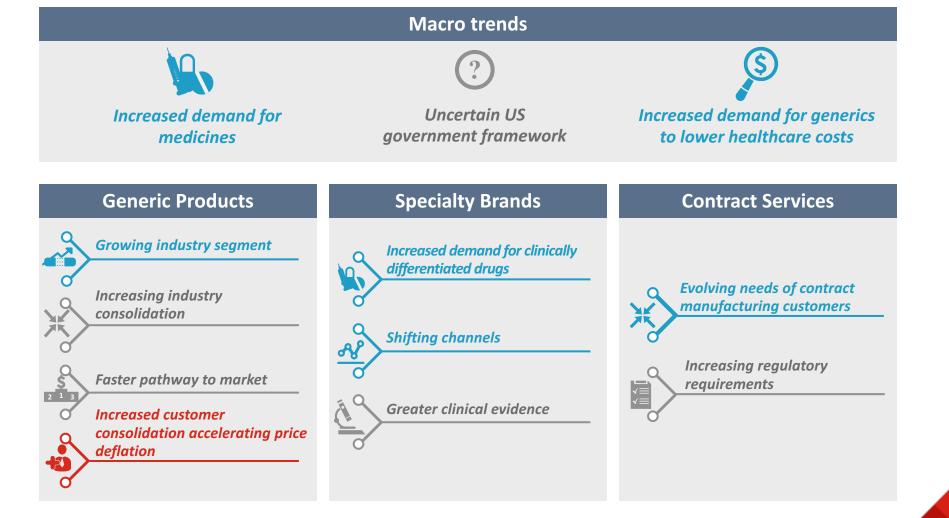
FY15

FY16

1H17 Ann



# The key trends relevant to Mayne Pharma are generally supportive...





# ...and, while the regulatory environment is complex, the anticipated impact is minor

Topic	Event	Mayne Pharma view	Impact on Mayne Pharma
Health Insurance	<ul> <li>President Trump is seeking to "repeal and replace" Obamacare</li> <li>Forced to pull legislation reform bill due to lack of support amongst the GOP</li> </ul>	<ul> <li>Unclear what Trump's next move will be, but any change is unlikely to fundamentally change the reimbursement mechanism</li> <li>If enacted with reduced patient insurance coverage will have a minor negative impact on drug volumes</li> </ul>	Minor negative impact
Food and Drug Administration (FDA)	<ul> <li>Trump appointed Scott Gottlieb, a physician, venture capitalist and government insider as FDA Commissioner</li> <li>Gottlieb has stated his priorities (if confirmed) will be combating opioid addiction and accelerating the approval of new drugs</li> </ul>	<ul> <li>Gottlieb is unlikely to change the regulatory environment given his background with the pharma industry</li> <li>Speeding the approval process of new drugs will reward players with strong pipelines and high quality dossiers</li> </ul>	Moderate positive impact
Pharma Pricing	<ul> <li>Several congressional investigations into pricing have commenced following pricing scandals (Valeant, Turing, Marathon)</li> <li>Trump has accused the industry with "getting away with murder"</li> </ul>	<ul> <li>Branded drugs: industry has begun self-regulating pricing (limiting price rises below explicit thresholds).</li> <li>Managed Care also reducing annual price increase to low-single digit</li> <li>Generic drugs: Net pricing has little relevance to official list pricing</li> </ul>	Minor negative impact



## We have a clear strategic ambition to 2021...















- Triple size of the business in revenue terms to >A\$1.5bn
- Double digit CAGR EPS growth
- R&D investment to return to ~8-10% of group revenue
- New products to drive revenue and earnings growth (US\$7bn pipeline¹)
- Business development to supplement organic growth

Underpinned by fundamental growth and operational platforms

**R&D** pipeline

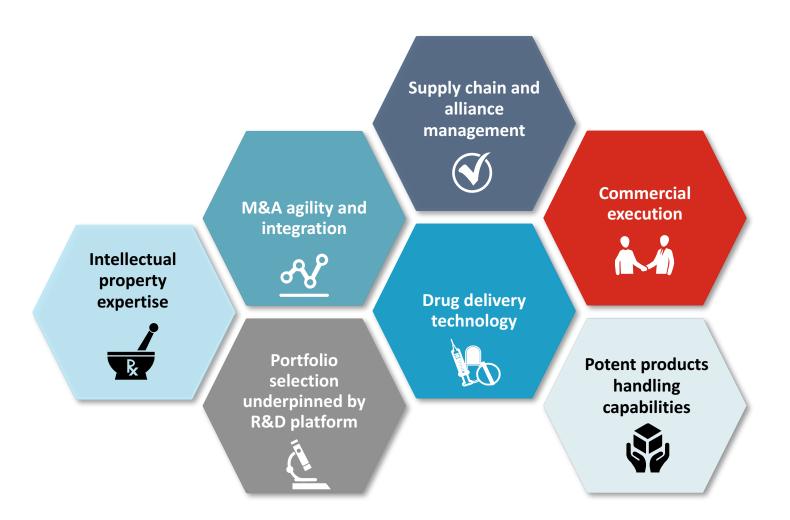
**M&A** execution

Scale and efficiency across operating segments

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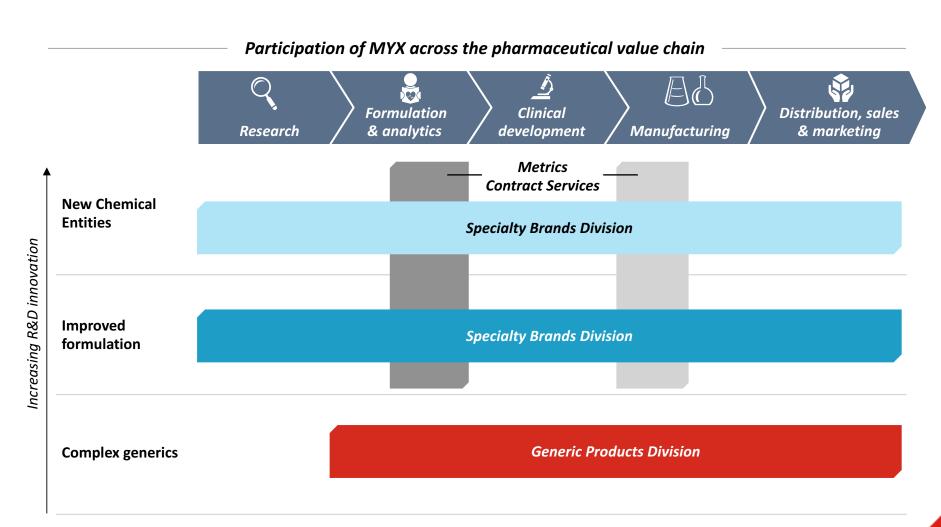


# ...and to achieve this ambition we will utilise our competitive advantages...





# ...leveraging our niche but diversified segment platform...





# ...that delivers a number of important synergy benefits...

	Synergies	Generic Products	Speciality Brands	Contract Services
	Earning stream diversification and stability	$\checkmark$	$\checkmark$	$\checkmark$
Scale	Efficiency sharing of central functions across BUs	$\checkmark$	$\checkmark$	$\checkmark$
	Cost effective access to capital	$\checkmark$	$\checkmark$	$\checkmark$
	Stronger negotiating power with customers and payers	$\checkmark$	$\checkmark$	
Capabilities	IP and technical expertise	$\checkmark$	$\checkmark$	$\checkmark$
	Therapeutic know-how	$\checkmark$	$\checkmark$	
	Drug delivery technology	$\checkmark$	$\checkmark$	$\checkmark$
	Commercial assets and channels to market	✓	$\checkmark$	
	Formulation / analytics expertise	$\checkmark$	$\checkmark$	$\checkmark$



# ...and is underpinned by an experienced leadership team



### **Scott Richards**

Chief Executive Officer
Actavis, Hospira, FH Faulding & Co.



### Nick Freeman\*

Group CFO & Company Secretary ANZ Bank, Qantas, Shell, KPMG



### **Gadi Ben-Nissim**

**EVP, Generic Products** *Teva* 



### **Craig Boyd**

**EVP, Specialty Brands** *Hospira, Mylan, Novartis* 



### **Peter Paltoglou**

EVP, Chief Development Officer Credit Suisse, Hindal



### **Eric Evans**

CFO, Mayne Pharma USA
AAIPharma, Patheon, Novartis, Sandoz



### **Stefan Cross**

Chief Commerical Officer Hospira, FH Faulding & Co



### Dr Ilana Stancovski

EVP, Chief Scientific Officer

Actavis, Pfizer



### John Ross

President, Mayne Pharma USA

CPL, Eli Lilly



### Kim McClintock

**EVP, Metrics Contract Services** *Alcami Corp, Banner Pharmacaps* 



### **Andrew Van Breugal**

**EVP, Operations** *Merck, Mediochemie, Douglas* 



### **Kate Rintoul**

**EVP and General Counsel** *Minter Ellison, Shell* 

\*Commencing 22 May 2017



## Our progress has been positive so far

# US Generic Products expansion

- Acquisition of generic product portfolio from Teva and Allergan
- Expansion of generics pipeline through strategic alliances (eg. Mithra, Corium)
- Launch of first Paragraph IV opportunity, dofetilide, which has become our largest selling generic product

## Specialty Brands expansion

- Successful acquisition and launch of patent-protected Fabior® and Sorilux® foams
- Advancing SUBA®-Itraconazole in anti-fungal and oncology

## Leverage and diversify drug delivery platforms

- Introduced foams as a new drug delivery technology
- Building additional development and commercial manufacturing capacity for modified release and potent compounds
- New strategic alliances to access high containment semi-solid, hormonal devices and transdermal patches

### **Commercial execution**

- Multichannel strategy to diversify earnings (specialty, government, telesales)
- Successful defence against generic event on Doryx® and capture of market share from new product launches (dofetilide, BUPAP, BAC tablet, Doryx® MPC, Fabior® and Sorilux®)

### **Operational excellence**

- Dual site capacity expansion underway in Greenville (NC) and Salisbury (SA) to improve product margins, quality and customer service
- Established strategic API sourcing capability to consolidate purchasing globally
- Rolled out new ERP system in the US

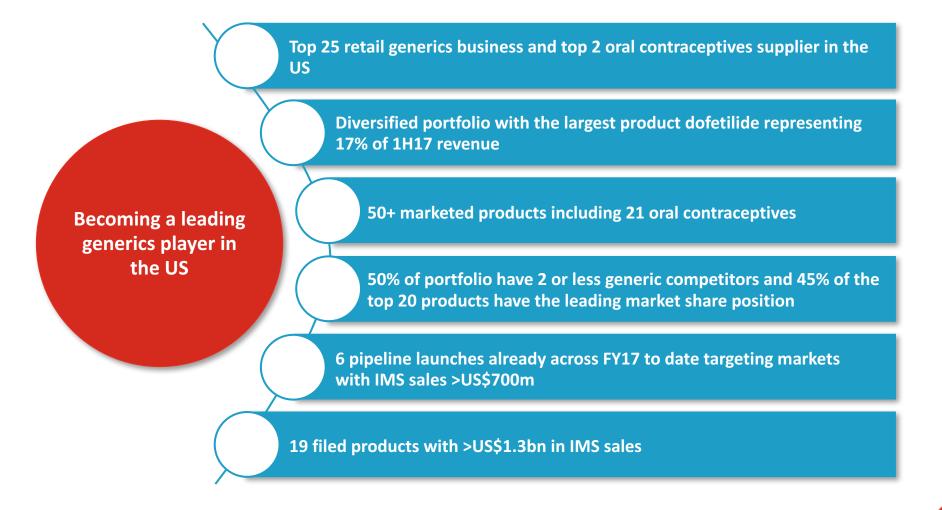


Generic Products Division (GPD)

Stefan Cross



### **Generic Products overview**

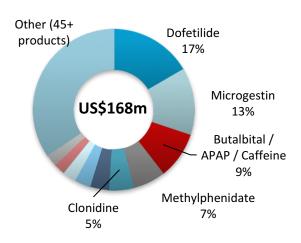


Source: IMS Health, MAT February 2017.



# Rapidly growing diversified portfolio with limited number of generic competitors

### 1HFY17 GPD revenue by family



# GPD product portfolio by number of generic competitors<sup>1</sup>

Only generic supplier	4%
One	25%
Two	23%
Three	6%
Four or more	43%

## **GPD** revenue and gross profit % (US\$m)<sup>2</sup>



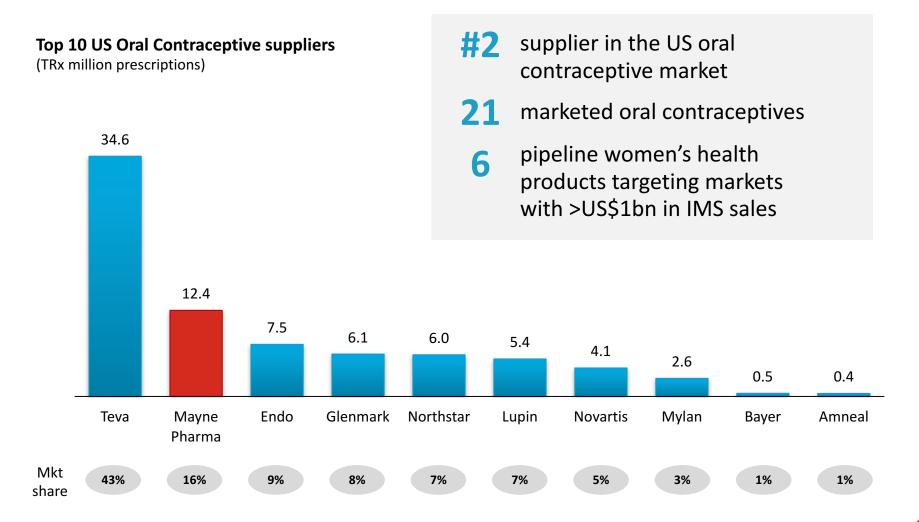
Source: IMS Health, MAT February 2017.

<sup>1.</sup> Gx competitors excludes Mayne Pharma.

<sup>2. 1</sup>H17 results annualised for ease of comparison; not to be used as guidance.



# Second largest provider of generic oral contraceptives in the US

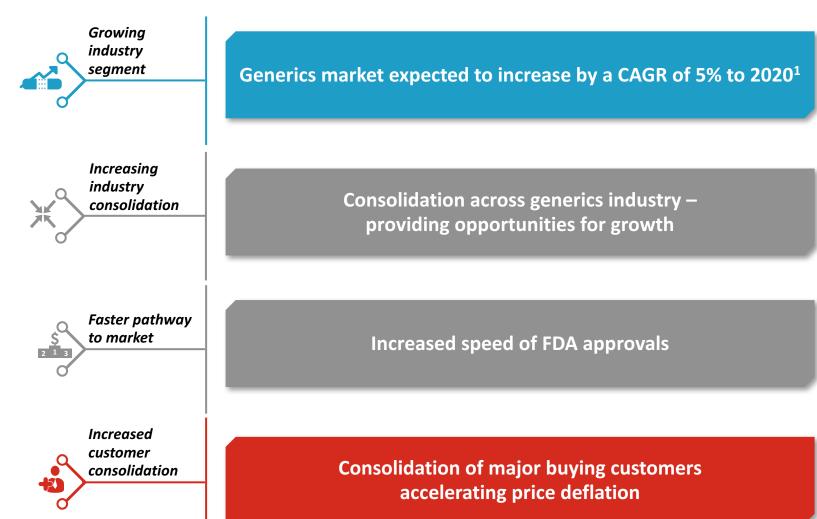


Source: IMS Health, MAT February 2017.

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## **Key market trends relevant to Generic Products**

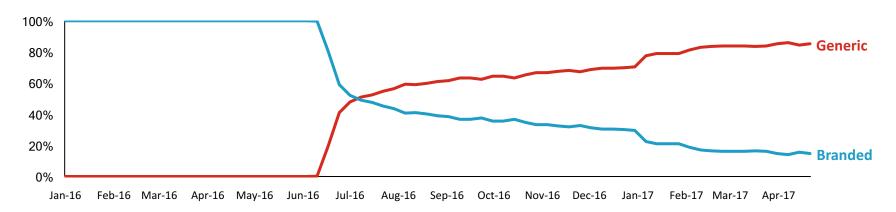




## **US** generic market pricing dynamics

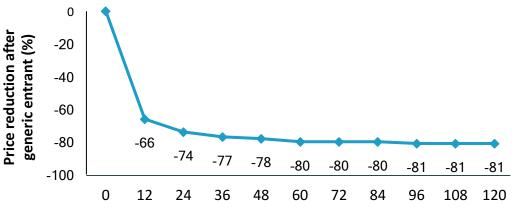
### Dofetilide generic entrant market share<sup>1</sup>

(TRx prescriptions)



### Average generic price is 60-70% below brand upon introduction and reaches 80-90% after 2-3 years

### Typical price reduction post generic entrants – oral medicines<sup>2</sup>



Months since loss of exclusivity

#### Source:

- 1. IMS Health weekly TRx as at 21 April 2017.
- 2. Generic Drug Report 2016. Drug Store News February 2016. Based on IMS Health data.



### **GPD** drivers of success





## Attractive pipeline to drive future growth

### **Today**

19 filed products with >US\$1.3 billion in IMS sales

6 launches expected this calendar year including a US\$250m first to market opportunity

20+ development projects with >US\$6 billion in IMS sales

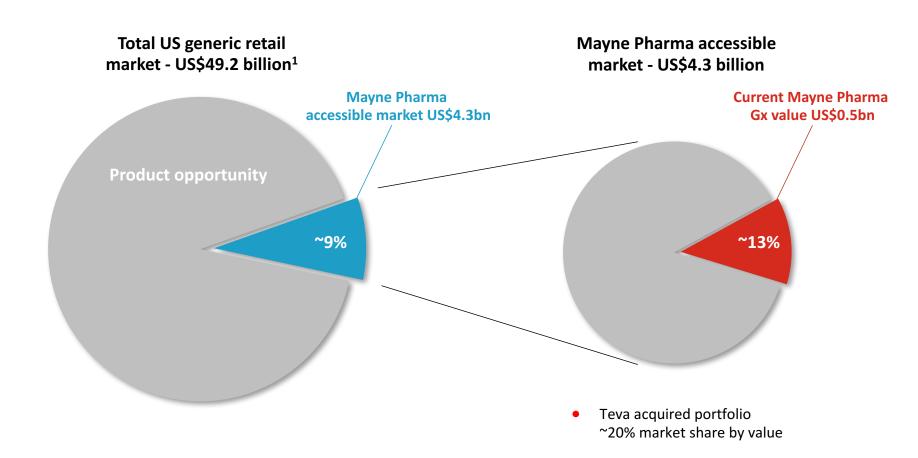
### **Future Total US pharma market** Strategic fit 2,500+ molecules US\$465bn **Profitability** First to market **Target Markets** Retail channel First to File Patent / PIV complexity Government Ability to (co) develop / manufacture **Ability to** Market size / growth execute **API** sourcing complexity Therapeutic focus Pipeline **Clinical complexity**

- Focused on internal development, supplemented with complementary co-development and licensing programs
- Majority of pipeline products are technically challenging to develop and manufacture and accordingly have low levels of current competition

Source: IMS Health, MAT February 2017.



# Mayne Pharma participates in only 9% of the total retail generics market

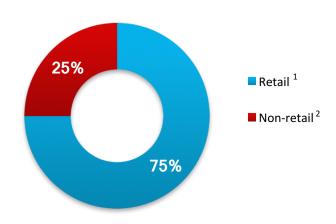


Significant opportunity to gain further market share across the portfolio



### Multichannel strategy to drive growth

### US generic sales by channel



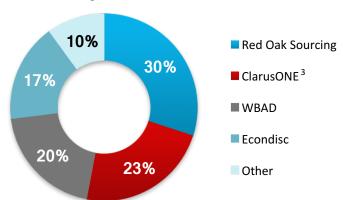
#### **Recent channel consolidation**

 There has been both consolidation and vertical integration, spanning wholesalers, retailers, Pharmacy Benefit Managers (PBMs) and global distributors



### **Retail customer segmentation**

Estimated US generics market mix



### **Channel expansion opportunities for Mayne Pharma**



Source: IMS Health, MAT February 2017 and internal analysis.

- 1. Retail includes chain and food stores, merchants and mail services.
- 2. Non-retail includes hospitals, clinics, long term care, home healthcare and federal facilities.
- 3. Pending approval of proposed transaction.



# Commercial execution – case study of dofetilide first-to-market launch

### **Pre-Approval** Significant pre-launch planning activities 6 June 2016 Mayne Pharma receives first generic approval to Pfizer's US\$200m Tikosyn® brand (dofetilide) Awarded 180-days of market exclusivity relating to a complete ANDA containing a Paragraph IV certification > 3 months of total market inventory released for sale to the market 7 June 2016 Customer orders received at our Raleigh, NC **Customer Service centre** Same day processing of orders Pick-pack-ship at logistics partner, DHL 8 June 2016 Customers received Mayne Pharma dofetilide capsules in pharmacy and warehouse 11:00am - 99%+ of product delivered By end June 2016 Secured over 60% of the market demand for dofetilide Defended against the launch of Pfizer's authorised generic

Source: IMS Health, MAT February 2017.



# Commercial execution – success with new product launches



62%
product
market share,
2 generic
companies



product
market share,
6 generic
companies



product
market share,
sole generic
company,
launched Feb
2017



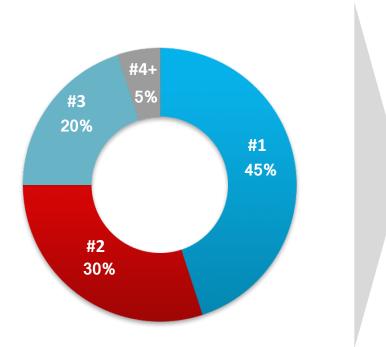
product
market share,
3 generic
companies,
launched Jan
2017



# Almost half of the top 20 products have leading market shares

### Mayne Pharma's market position in top 20 products

(NSP ext units, last quarter market share)



We are a top 3 player in 95% of our top 20 products

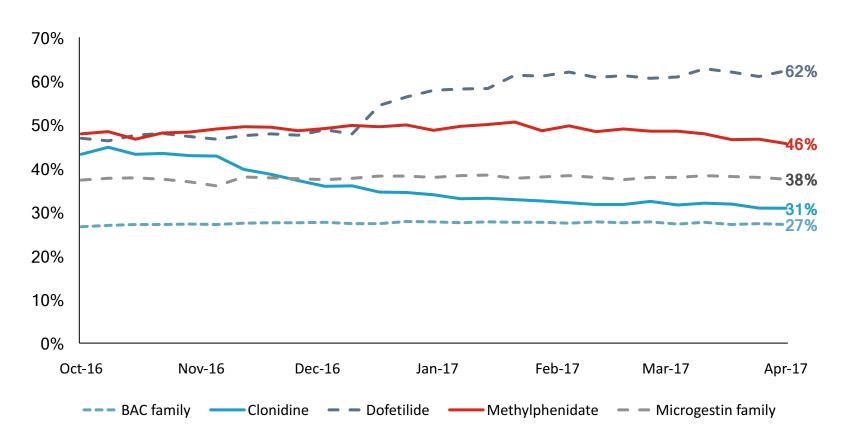
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# Commercial execution – strong market share from top 5 products

### Top 5 generic portfolio product market share

(TRx prescriptions)



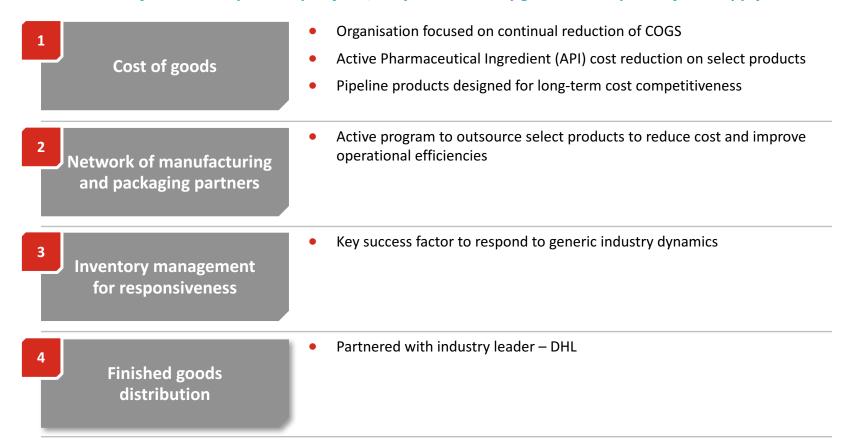
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Source: IMS Health, weekly TRx as at 21 April 2017.



# Supply chain excellence – scaled and ready for continued growth

In readiness for the Teva product portfolio, Mayne Pharma upgraded all aspects of the supply chain



Cost savings of US\$12m expected to be extracted from supply chain optimisation of the Teva acquired products



## **Key takeaways – Generic Products**

Diversified portfolio with leading market shares

Top 25 retail generics business and top 2 oral contraceptives supplier in the US

Cost savings of US\$12m expected to be extracted from Teva product acquisition by FY19

Targeting double digit 5-year revenue CAGR - driven by pipeline, new channels and expanding market share

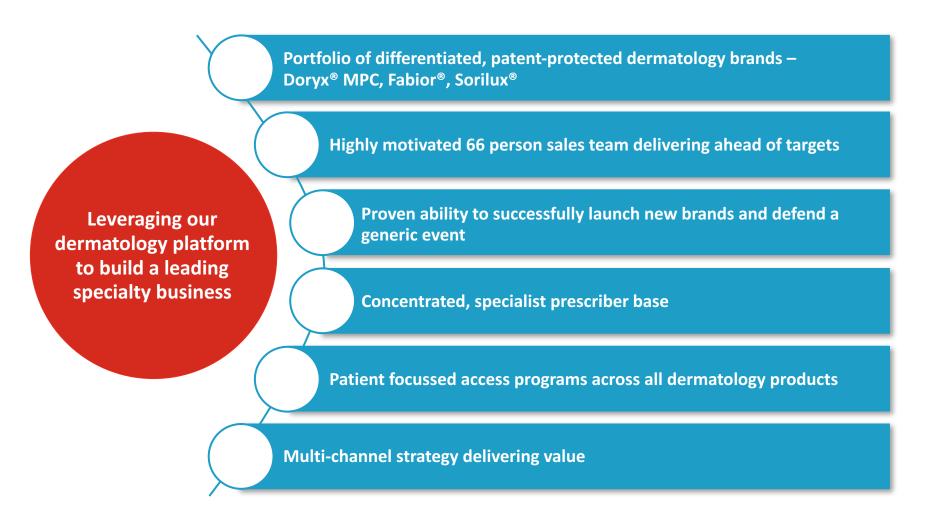


**Specialty Brands Division (SBD)** 

Craig Boyd

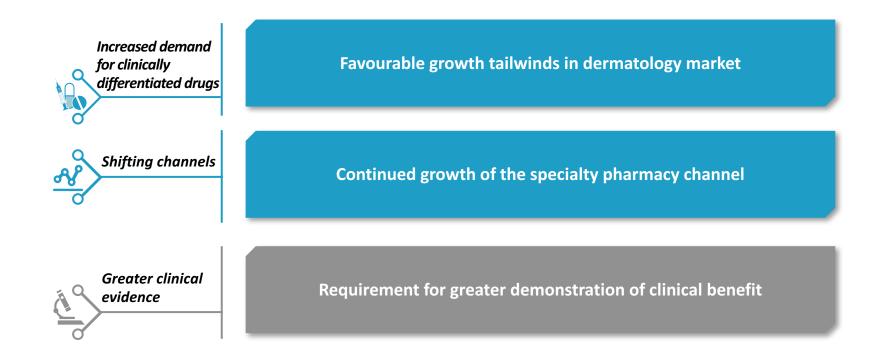


### **Specialty Brands overview**





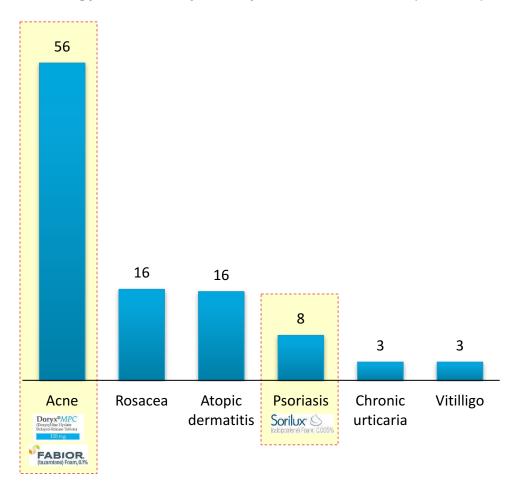
### **Key market trends relevant to Specialty Brands**





### **US Dermatology market overview**

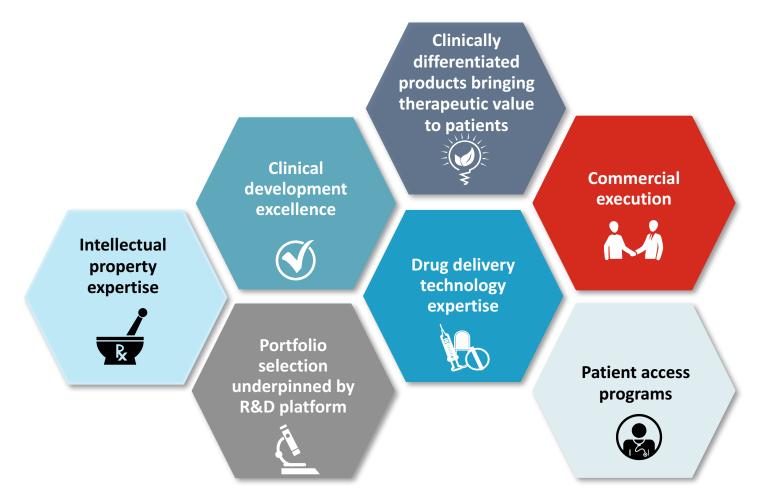
#### **Dermatology disorders – patient prevalence in the US (millions)**



- Dermatology pharmaceutical market size estimated at ~US\$14bn
- Acne and psoriasis sub markets represent ~30% of the total dermatology market value
- Acne and psoriasis prevalent in more than 60 million people
- Topical and oral dosage forms account for ~95% of the dermatology pharmaceutical market
- No NCE in acne in the US market in the last 15 years
- ~10,000 target dermatologists

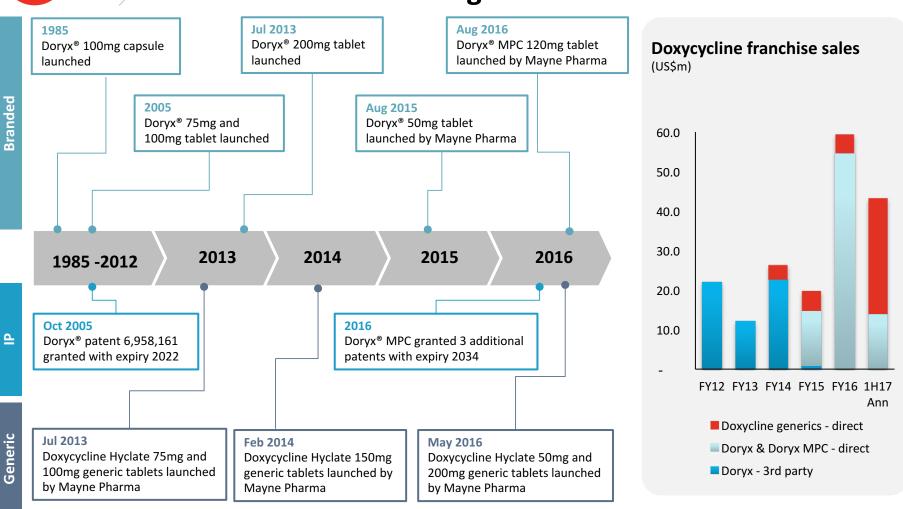


#### **SBD** drivers of success





# Doxycycline franchise has delivered sustained revenue and earnings over time



Doxycycline franchise highlights our ability to extract value from the creation of new IP, improved formulations and defending against generic competition



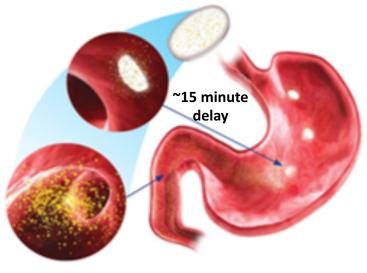
## Doryx® MPC – new formulation that further retards the release of doxycycline in the stomach

**Doryx**®MPC (Doxycycline Hyclate Delayed-Release Tablets)

120 mg







The modified polymer coat further delays absorption of Doryx® MPC into the GI tract by approximately 15 minutes



## Doryx® MPC competes in the tetracycline acne market

Product	Company	Molecule	Form	Average TRx / week	Mkt share	IP
Doryx <sup>®</sup> MPC	mayne pharma	Doxycycline	Tablet MR	1,900	8%	3 additional patents with 2034 expiry
Doryx <sup>®</sup>	maynepharma	Doxycycline	Tablet MR	250		Generics launched
Authorised generics	maynepharma	Doxycycline	Tablet MR	2,600		N/A
Acticlate	<b>E</b> Almirall	Doxycycline	Tablet IR	7,100	12%	None
Solodyn	VALEANT	Minocycline	Tablet MR	8,400	14%	Generics expected to launch in 2018 <sup>1</sup>
Generics	Multiple	Doxycycline	Capsules / Tablet IR and MR	40,500	66%	N/A

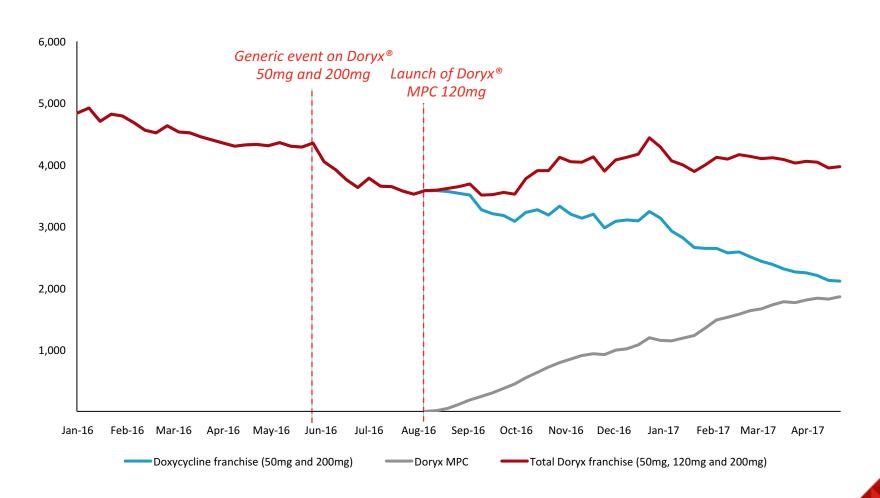
Significant opportunity to continue to grow Doryx® MPC sales through improved sales force execution and promotion



## Doryx® MPC has become a material part of the doxycycline franchise driving overall growth

Doxycycline franchise weekly TRx (brand and generic)

(4 week rolling)

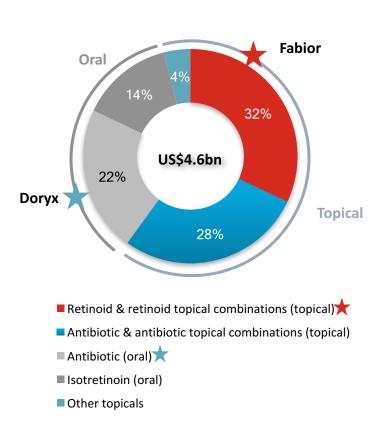


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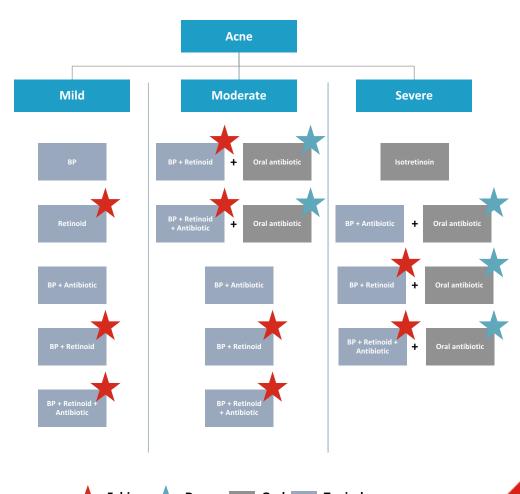


## Fabior® and Doryx® are highly complementary acne products

#### US acne market by value



#### First line acne treatment





## Fabior® – the only topical retinoid in a foam formulation

Fabior® can be applied to skin of the face and upper trunk











### Fabior® marketing aid – launched January 2017



#### Indication

Fabior® (tazarotene) Foam is a retinoid indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

#### Important Safety Information

FABIOR Foam is contraindicated in pregnancy because tazarotene is a teratogenic substance. FABIOR Foam may cause fatal harm when administered to a pregnant woman. If the patient becomes pregnant while using this drug, treatment should be discontinued and the patient apprised of the potential hazard to the fetus Females of child-bearing potential should be warned of the potential risk and use adequate birth-control measures to avoid pregnancy. A negative serum or urine result for pregnancy test should be obtained within 2 weeks prior to therapy with FABIOR Foam; therapy should begin during a normal mension.

- FABIOR Foam should be used with caution in patients with a history of local tolerability reactions or local hypersensitivity.
- Retinoids should not be used on abraded or eczematous skin, as they may cause severe irritation. Contact with the
  mouth eyes, and mucous membranes should be avoided. Weather extremes, such as wind or cold, may be more
  irritating to patients using FABIOR Foam. Excessive topical application of FABIOR Foam may lead to marked redness,
  peeling, or discomfort

Please see Important Safety Information throughout and Full Prescribing Information enclosed. This information is also available at Fabioc.com.





## Fabior® competes in the topical retinoid acne market

Product	Company	Molecule	Form	Average TRx / week	Mkt share	IP
Fabior®	mayne pharma	Tazarotene	Foam	1,200	1%	Patent expires 2030
Tazorac	<b>Allergan</b>	Tazarotene	Gel / cream	6,000	5%	Generics launched
Epiduo / Epiduo Forte	♣ GALDERMA	Adapalene / Benzoyl Peroxide	Gel	19,000	17%	Multiple patents
Veltin	<b>E</b> Almirall	Clindamycin Tretinoin	Gel	3,000	3%	None
Retin A / Retin A Micro	VALEANT	Tretinoin	Cream / gel	5,700	5%	Generics launched
Ziana	VALEANT	Clindamycin Tretinoin	Gel	1,250	1%	Generics launched
Differin	♣ GALDERMA	Adapalene	Cream / gel / lotion	1,600	1%	Multiple patents
Other brands	Multiple	Multiple	Multiple	900	1%	N/a
Generics	Multiple	Multiple	Multiple	74,500	66%	N/a

Significantly greater market opportunity for Fabior® than Doryx® MPC

Source: IMS Health, 4 week average TRx / week.



# Sorilux® – the only vitamin-D, non steroid foam for the treatment of scalp and body psoriasis

Sorilux® can be applied to the scalp and body











### Sorilux® marketing aid – launched January 2017



## FOR SCALP AND BODY PSORIASIS, **SORILUX FOAM DELIVERS**

- The only single-agent calcipotriene available in a foam<sup>1</sup>
- Steroid-free therapy
- Calcipotriene in an elegant foam formulation
  - Penetrates the skin barrier to deliver the molecule into the epidermis and dermis<sup>2</sup>
  - · Aqueous-based emulsion
  - · No ethanol, preservatives, or fragrances
  - Easy to apply to both hair-bearing and non-hair-bearing areas<sup>3</sup>
  - Absorbs quickly without greasiness or residue<sup>2,3</sup>

#### Indication

SORILUX Foam is indicated for the topical treatment of plaque psoriasis of the scalp and body in patients 18 years and older.

#### **Important Safety Information**

- SORILUX Foam should not be used by patients with known hypercalcemia
- The propellant in SORILUX Foam is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application
- Transient, rapidly reversible elevation of serum calcium has occurred with use of calcipotriene. If elevation in serum calcium outside the normal range should occur, discontinue treatment until normal calcium levels are restored
- · Physicians may wish to limit or avoid use of phototherapy in patients who use SORILUX Foam

Please see Important Safety Information throughout and Full Prescribing Information enclosed. This information is also available at SORILUXFoam.com





# Sorilux® competes in the topical Vitamin D psoriasis market

Product	Company	Molecule	Form	Average TRx / week	Mkt share	IP
Sorilux <sup>®</sup>	maynepharma	Calcipotrene	Foam	230	2%	Patents expire 2026 and 2028
Enstillar	L E O	Betamethasone / calcipotrene	Foam	1,800	12%	Multiple patents
Taclonex	L E O	Betamethasone / calcipotrene	Suspension / ointment	1,800	12%	Multiple patents
Calcitrene	TARO	Calcipotrene	Ointment	60	0%	Generics launched
Dovonex	L E O	Calcitriol	Cream	30	0%	Generics launched
Vectical 🕹	GALDERMA	Calcipotrene	Ointment	70	0%	Generics launched
Generics	Multiple	Multiple	Multiple	10,700	74%	N/a

Sorilux® provides a new complementary psoriasis therapeutic market opportunity to penetrate

Source: IMS Health, 4 week average TRx / week.

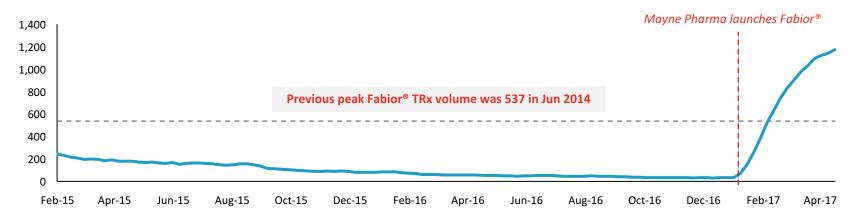
52



## Fabior® and Sorilux® are both gaining significant prescriber adoption

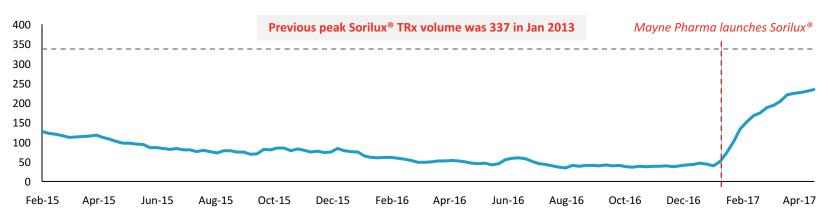
#### Fabior® weekly TRx since launch

(4 week rolling)



#### Sorilux® weekly TRx since launch

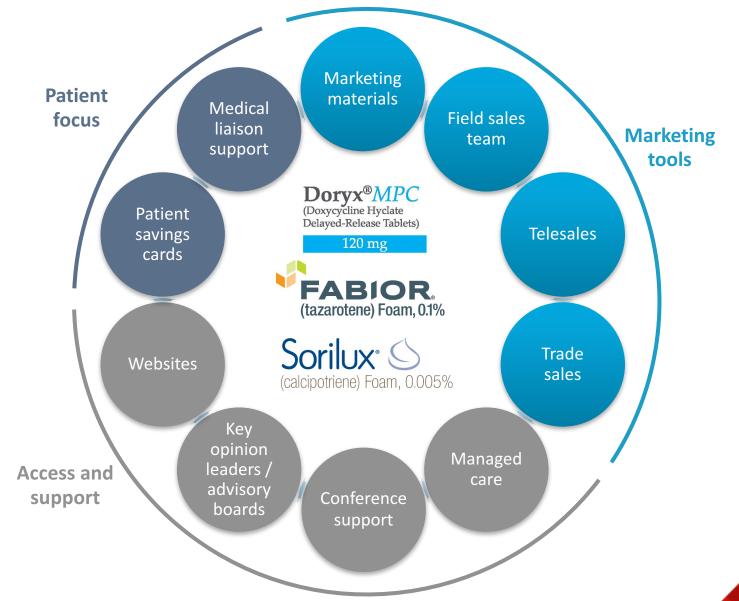
(4 week rolling)



53

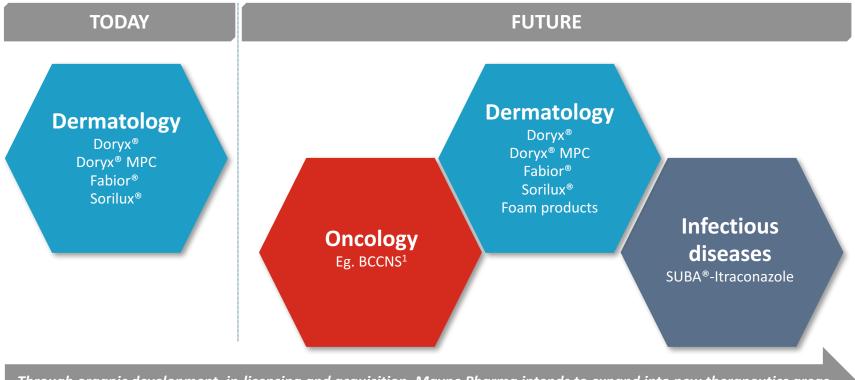


## Multifaceted marketing campaigns driving sales force effectiveness





## Mayne Pharma will expand its specialty brand portfolio through organic and inorganic initiatives



Through organic development, in-licensing and acquisition, Mayne Pharma intends to expand into new therapeutics areas

- Mayne Pharma's therapeutic platforms will be built from products that leverage the Company's development and manufacturing capabilities
- Partnerships with HedgePath Pharmaceuticals and Formulytica are broadening the branded pipeline
- Mayne Pharma remains committed to the development of new specialty brands employing its drug delivery know-how, built on a patent strategy protecting the Company's investment



### **Key takeaways – Specialty Brands**

Portfolio of clinically differentiated products that bring therapeutic value to patients

Business now positioned for strong future growth

Expand product portfolio through internal product development, inlicensing and acquisition

Driving category leadership in dermatology through commercial execution



**Metrics Contract Services** 

John Ross



### **Metrics Contract Services overview**



100+ high quality and long term 'fee for service' clients base across the pharmaceutical and biotechnology sectors

Leading oral dosage form CDMO for novel drug products

Supported by 130 analytical chemists and formulators

Offering analytical services, formulation development and manufacturing services

Significant productivity improvements from analytical laboratory efficiency program

Track record of strong financial performance with revenue up 36% over last 2 years with expanding gross profit margins



### **Key market trends relevant to Contract Services**



**Propensity to outsource continues to rise in target segments** 

**Consolidation of commercial CMOs** 



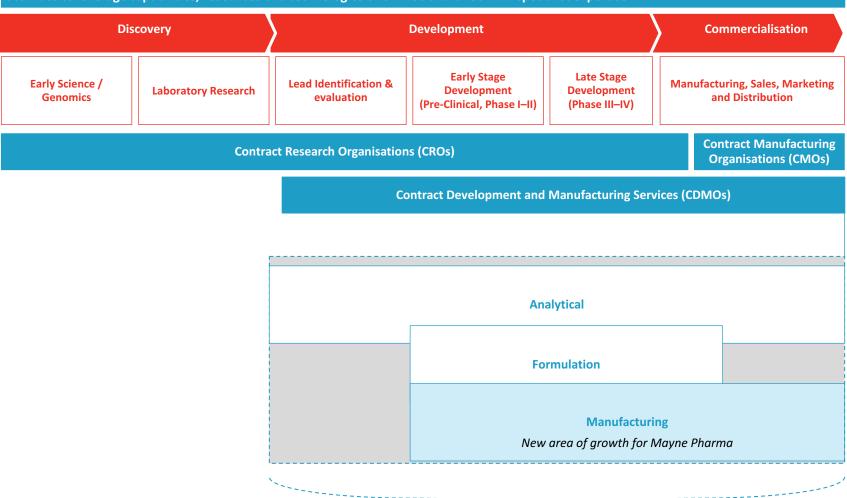
**Increasing regulatory hurdles** 

**Challenges for low-cost providers in developing nations** 



#### **Contract services market**

The Contract Services market has grown into a substantial market as a result of pharmaceutical companies outsourcing drug development activities to leverage capabilities, resources and technologies of CDMOs and CROs with specialist expertise





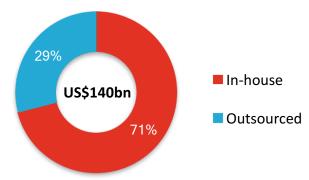
## CDMO market is highly fragmented with attractive fundamentals

- US CDMO market continues to grow 6-7% per annum
- US\$140b global R&D spend for pharmaceutical and biotechnology industry of which ~30% outsourced
- R&D pipelines up 50% over last five years
- >12,000 drugs in pre-clinical to phase III development globally
- Highly fragmented industry with Top 5
   CMOs accounting for <20% of the global market</li>
- Estimated ~60-90% of molecules entering development today require advanced delivery technologies

#### Top 5 Global CMO market share

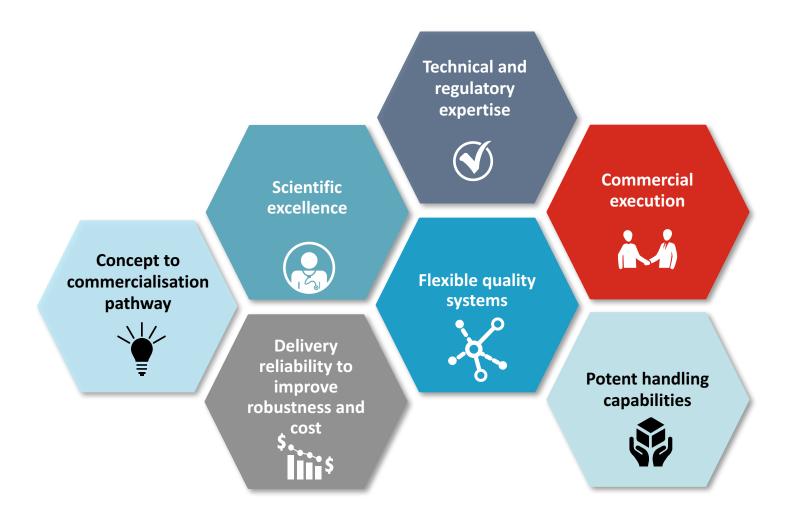
СМО	Market share
Catalent	5%
Patheon	4%
Lonza	4%
West Pharmaceutical	4%
Cambrex	1%

#### Global outsourcing opportunity





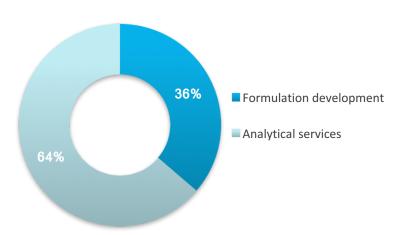
### MCS drivers of success



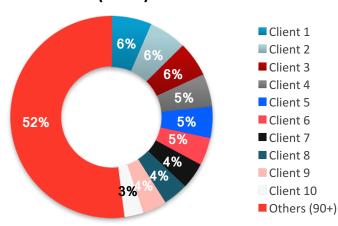


## Diversified client portfolio with strong historical financial performance

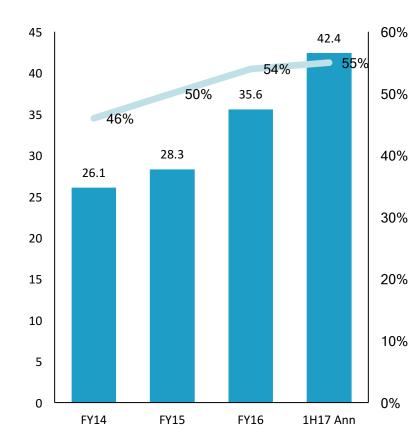
#### MCS sales by service area (1H17)



#### MCS customer mix (1H17)



### MCS revenue and gross profit % (US\$m)<sup>1</sup>



<sup>1. 1</sup>H17 results annualised for ease of comparison; not to be used as guidance.



### MCS products at all stages of development

**Potential pipeline of** future commercial manufacturing contracts Phase I Phase II **Phase III** Commercial<sup>1</sup> 34 37 **23 Products** 27 23 **27 13** Clients

<sup>1.</sup> Mayne Pharma provides analytical services for these commercial clients.



## MCS outlook remains very strong with key performance indicators trending favourably

Increasing project value reflecting later stage, higher margin development work



Committed business pipeline<sup>1</sup> up 25% over last 12 months



17 commercial manufacturing quotes with peak unit demand ~90m units



### **Investing for growth**

#### **Operational efficiencies Expanding capabilities Increased capacity** Multi-particulate coating Analytical services revenue New stability storage facility, triples current per employee increased 20% Bead-coating fluid bed capacity since implementing a technology laboratory efficiency Following facilities program in the second half Solvent-based processes expansion in Greenville, of FY16 MCS footprint will increase High potency compounds by 85% including 10 new Laboratory efficiency analytical laboratories and program recently expanded Gerteis roller compaction to other divisions development suites Lean principles applied to CTM manufacturing spaces expected to increase output by more than 25%



# Greenville capital investment program progressing to plan

New fluid bed spray coater now installed in development laboratories in Greenville



New stability centre facility at Greenville







### **Key takeaways – Metrics Contract Services**

Strong revenue and earnings momentum

Redevelopment of Greenville facilities creating significantly expanded capacity for MCS

Broadening oral solid dose capabilities through facilities expansion

Scope for "bolt-on" acquisitions in a highly fragmented market



## 5 Global Operational excellence

John Ross



### **Operational excellence overview**

Outstanding track record with FDA and TGA

Successful transition of acquired Teva product portfolio with no supply chain disruptions

Focus on efficiency, quality, cost control and asset utilisation

Lost time injury frequency rate reduced by 25% in 2016 versus prior year

A\$130m two site capacity and capability expansion on track for completion in 2018

In 2016 there were 51 regulatory and customer inspections / audits across manufacturing sites with zero critical observations

New US Enterprise Resource Planning (ERP) system improving productivity, efficiency, analytics and controls



## **Operational excellence drivers of success**





## Key achievements

	Improvement	Benefit
API sourcing	<ul> <li>Strategic API sourcing function established in advance of Teva portfolio acquisition</li> </ul>	<ul> <li>Consolidation of global purchasing of API</li> <li>Key contributor to Teva deal synergies</li> </ul>
Tech transfer	<ul> <li>Strengthened supply team and connectivity between other departments to ensure reliability of supply and smooth transition from Teva</li> </ul>	<ul> <li>Improved customer service and supply chain reliability</li> </ul>
Supply chain	<ul> <li>Tech transfer plans developed and advancing for 27 Teva acquired products</li> </ul>	<ul> <li>On track for first products to be transferred in 2017 with US\$12m of cost savings to be realised by FY19</li> </ul>
Manufacturing	<ul> <li>Two site capacity and capability expansion underway coupled with Lean pursuits</li> </ul>	<ul> <li>Expected to reduce product cost for select products that would otherwise have been outsourced, improve quality and service levels</li> </ul>
Systems	<ul> <li>Rolled out new US Enterprise Resource Planning (ERP) system</li> </ul>	<ul> <li>Improved productivity and efficiency through forecast accuracy, integrated S&amp;OP and supply chain visibility</li> </ul>



### Supply chain built around quality and reliability

#### **Major API Suppliers**



















Greenville, NC Salisbury, Australia



#### **Key CMO Suppliers**



















**FTC Transitional Supply** 





### **Teva technology transfer status**

#### **Products to be transferred**

Amethia Lo Fentanyl Buccal

Azurette Maytessa

Budesonide ER Microgestin® 1/20
Camila Microgestin® 1/20 FE

Carbidopa/Levodopa Microgestin® 1.5/30 Caziant Microgestin® 1.5/30 FE

Clarithromycin ER Necon

Clozapine Nortriptyline
Dextroamphetamine ER Tamoxifen
Disopyramide Tilia FE

Diazepam Trimethoprim

Errin Zarah Estazolam Zovia

Estradiol

Forecast approvals		
mayne pharma	4x FY18 5x FY19	
	1x FY20	
© CHEMO	4x FY18	
	5x FY19	
rPatheon.	2x FY18	
Performance the World Over	1x FY19	
Piramal   Pharma Solutions	4x FY18	
knowledge action care	1x FY19	

On track for cost savings of US\$12m to be realised across 27 tech transfer programs



## Significant investment in commercial manufacturing

#### **Greenville site expansion**

#### **Summary**

- US\$80m new solid oral dose 125,000ft<sup>2</sup> manufacturing facility in Greenville underway
- Commissioning and validation across 2017
- Site operational 1Q 2018



#### Benefits of site expansion

- More than doubles operational footprint to 225,000ft<sup>2</sup>
- Creates new capacity and capability in the US to accelerate growth
- Adds multi-particulate layering, bead coating fluid bed technology, organic solvent coating capacities and handling of high potent compounds
- Raises total annual capacity from 250m doses to over 1bn
- Control manufacture, packaging and distribution of key product franchises
- Supports MCS expected growth in analytical services, formulation development and commercial manufacturing
- Segregation of commercial and non-commercial activities



## Significant investment in commercial manufacturing

#### Salisbury site expansion

#### **Summary**

- A\$25m investment in Salisbury to expand fluid bed processing capacity and add new potent handling capability
- Construction underway with completion in 1Q 2018



#### Benefits of site expansion

- Creates additional modified-release manufacturing capacity to support expected growth in currently marketed products, pipeline products filed and to be filed with regulatory agencies around the world
- New capability in potent handling to support the transfer inhouse of products from the Teva portfolio



### Long-term vision for operational excellence

Drive cost improvements and asset utilisation efficiency

Deliver on price,
quality and
availability to meet
customer
expectations

Enhance processes around product supply, production and distribution

Develop
organisational
competency in Lean
manufacturing
systems and supply
chain excellence



Research & Development

Ilana Stancovski



#### **R&D** overview

65 R&D team members in Australia and US

'Portfolio centric' approach to product

selection

Expanding core capabilities – modified-release, potent, improved bioavailability, foam

Increasing focus on complex co-development programs and generic programs with clinical end point studies

80%+ of pipeline are potent and/or complex formulations

Investment in R&D has seen a seven-fold increase since 2012

40+ US pipeline with IMS sales greater than US\$7bn of which 19 are pending at the FDA

Source: IMS Health, MAT February 2017.



### **Key recent achievements**

#### **Product**

#### **Jun 16**

Approval and launch of dofetilide capsules – first Mayne Pharma PIV product to receive 180-days of marketing exclusivity

#### IΡ

#### **Jul 16**

A\$26m settlement on patent litigation with Forest Laboratories

#### **Alliances**

#### **Feb 17**

Strategic alliance with Formulytica – exclusive partner for development in medical dermatology

#### **Aug 16**

Launch of Doryx® MPC tablets, new formulation of doxycycline

#### 2016

Three Doryx® MPC patents covering the new drug formulation granted by the US PTO

#### **Feb 17**

Partnership with Mithra for Myring® (generic NuvaRing®), a hormonal contraceptive device

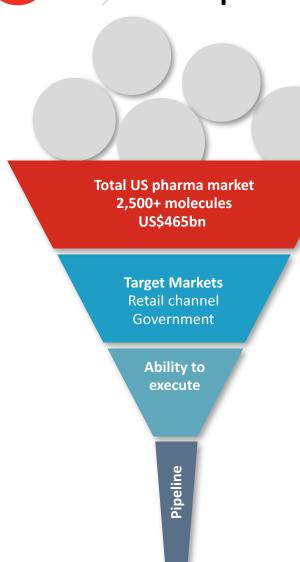


### **R&D** drivers of success





## Focused portfolio selection leverages capabilities globally - generics



#### Generic portfolio selection considerations

Strategic fit **Profitability** First to market First to File Patent / PIV complexity Ability to (co) develop / manufacture Market size / growth **API** sourcing complexity Therapeutic focus **Clinical complexity** 

Source: IMS Health, MAT February 2017.

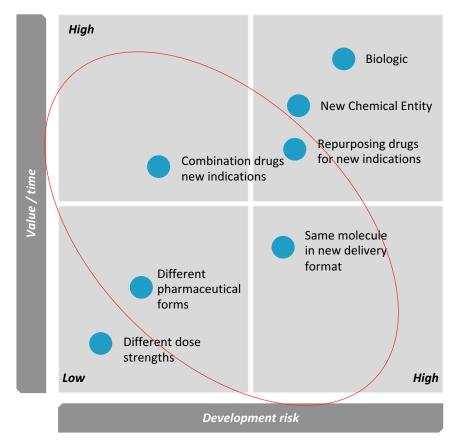


## Focused portfolio selection leverages capabilities globally – specialty brands

#### **Specialty Brands therapeutic focus**

## **Dermatology** Dorvx<sup>®</sup> Doryx® MPC Fabior® Sorilux<sup>®</sup> Foam products **Infectious** diseases SUBA®-Itraconazole Oncology Eg. BCCNS<sup>1</sup>

#### **Development of branded products**



Where M

Where Mayne Pharma has invested in R&D



## Increasing complexity of dosage forms in product portfolio

		Pipelille	ie products	
	Marketed product examples	2012	Today <sup>1</sup>	
Other differentiated dosage forms	Cyclosporine soft gel capsule	-	5	
Hormonal device		-	1	
Foam	Fabior®, Sorilux®	-	3	
Transdermal	Clonidine, fentanyl	-	2	
Topical creams / ointments	Percutane®, Myxazole®, fluocinonide	✓	5	
Potent	Liothyronine, dofetilide, tamoxifen, 21 oral contraceptives	✓	8	
Modified-release drug delivery	Doryx®, Kapanol®, Lozanoc®, Astrix®, Eryc®, budesonide, methylphenidate, dextroamphetamine	✓	7	
CIIs tablet / capsule	Methamphetamine, oxycodone, hydrocodone, morphine sulfate, diazepam	✓	9	
Immediate release tablet / capsule	BAC, carbidopa/levodopa, nortriptyline, amiodarone, trimethoprim	✓	23	

<sup>1.</sup> Some products are represented in multiple categories, and therefore numbers do not reconcile to 40+ pipeline products.

**Pipeline products** 



### Foams – a new complex delivery platform

#### Why foams?

- Fits therapeutic focus in dermatology
- Product development and manufacturing complexity
- Elegant delivery mechanism
- Well tolerated by patients
- Potential to reduce dose

#### F 0 R M ulytica

- AU based 'foam' formulation and development specialists
- Key scientists involved in development of Stiefel foam portfolio acquired by GSK in 2009
- Developing 3 early stage foam assets in partnership with Mayne Pharma



- US-based foam CMO
- Mayne Pharma acquired GSK foam line that is being installed at Pharmasol
- Strategic partnership developed to provide long term solution for foam pipeline products
- Equipment transfer & installation underway

#### Foam platform opportunities

#### **Improved formulations**

Through improved efficacy, tolerability and / or ease of application

#### **New indications**

Repurposing existing molecules into new therapeutic areas

#### **Generics**

Leveraging Mayne Pharma's Generic Products division and investment in the foam platform



### **R&D** strategic alliances expanding capabilities

#### Alliances established in the last 12 months



#### mithra

#### Corium





JM 🛠 Johnson Matthey

**Complementary** capabilities

- Manufacturing and development capabilities in soft gel, semi solid and high containment
- Focused on development of women's health hormonal devices
- **Provides** alternative drug delivery technology in transdermal patches

Clonidine patch (#5

marketed product)

relaunched Mar 17

Fentanyl patch

Provides alternative drug delivery technology in foam

Inventors of

Fabior® and

Sorilux® foam

- Clinical development partner
- Provides differentiated API capabilities

**Mayne Pharma** marketed products

- Hormonal topical
- Dermatology
- Myring<sup>®</sup> hormonal contraceptive device
- Transdermal
- 3 early stage foam candidates
- SUBA®-Itraconzole in oncology
- Dofetilide capsules (#1 marketed product)
- Methamphetamine tablets
- Oxycodone

**Pipeline products** 

- women's health
- topical

- patches

Potent oral product

**Pipeline** opportunity US\$620m+ market size

US\$770m+ market size

US\$620m+ market size

US\$100m+ market size

US\$50m+ market size

Mayne Pharma provides commercial, regulatory, IP, development, clinical expertise to these alliances

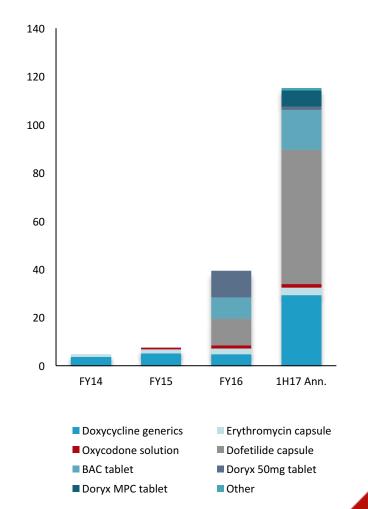
Source: IMS Health, MAT February 2017. 86



## Steady stream of product launches driving earnings growth

#### **Specialty Brands Generic Products** Doxycycline hyclate 75mg, 100mg and 150mg DR tablets **FY14** Erythromycin 250mg DR capsules Oxycodone oral solution **FY15** Dofetilide capsules Dorvx® 50mg DR tablets BAC tablet Doxycycline hyclate 50mg and 200mg DR tablets **FY16 BACCP** capsules Morphine sulfate ER tablet Doryx<sup>®</sup> MPC 120mg DR Temozolomide capsules tablet Budesonide 3mg ER capsules Fabior® foam **FY17 Butalbital/APAP** tablets Sorilux® foam Amiodarone 100mg tablets Methylphenidate 60mg capsule 19 products pending at FDA SUBA®-Itraconazole targeting markets with IMS Health Multiple early stage medical sales of US\$1.3bn dermatology opportunities **Pipeline** 20+ products still to be filed targeting markets with IMS Health

## Sales from new product launches since FY14 (US\$m)<sup>1</sup>



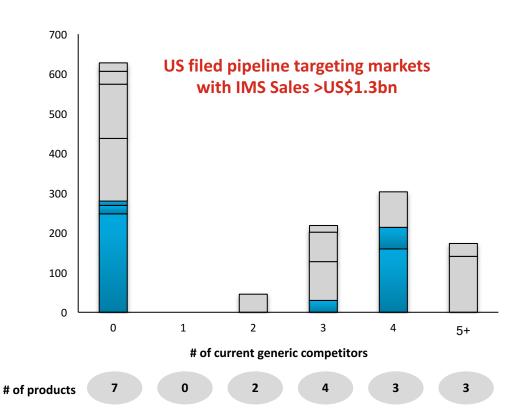
sales of US\$6bn



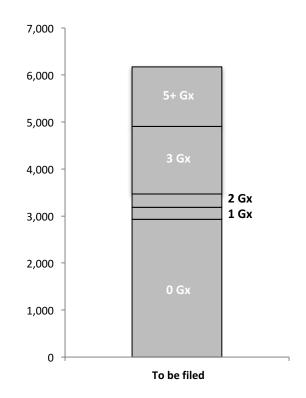
### Mature US generic pipeline

#### US filed pipeline by # of generic competitors (US\$m)

Expected launch in 2017



## US to be filed pipeline by # of generic competitors (US\$ millions)



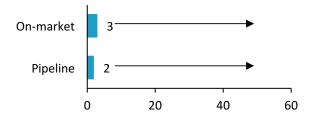
Source: IMS Health, MAT February 2017.



## **R&D** risk varies across the business segments



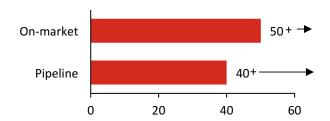
#### **Branded product portfolio**



#### **R&D** investment areas

- Oral dose reformulation of existing drugs
- Non-oral reformulation (e.g. creams, foams) of existing drugs
- Repurposing of existing drugs for other indications with clinical relevance

#### Generic product portfolio



- Complex generics
- Paragraph IV
- First-to-market



## SUBA-Itraconazole franchise has multiple opportunities for growth...

#### **Anti-fungal**

- Itraconazole is a broad spectrum anti-fungal used to treat both superficial and systemic infections
- Mayne Pharma's itraconazole based on SUBA® drug delivery technology (improved solubility)
- Approved in Australia, Spain, Germany, UK, Italy, Portugal, Belgium and Austria
- Marketed by Mayne Pharma in Australia and ISDIN in Germany and Spain
- Has been out-licensed in 15 countries around the world
- Expected to file in the US and launch in Austria,
   Columbia, Belgium, Italy, Mexico, Portugal in FY18
- Key itraconazole markets >US\$200m

#### Oncology

- Itrazoconazole has anti-cancer properties based on inhibition of the Hedgehog Signaling Pathway
- Partnered with Hedgepath Pharmaceuticals (market capitalization of US\$100m+) to pursue the clinical development, registration and commercialisation of SUBA®-Itraconazole in anticancer applications
- Mayne Pharma owns 50%+ of Hedgepath

#### **BCCNS**

- Unmet clinical need in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS)
- FDA granted Orphan Drug Designation for SUBA®-Itraconazole for treatment of patients with BCCNS
- Ongoing US Phase IIb multi-centre clinical trial
- Targeting 505b2 registration pathway
- Market potential in excess of US\$100m for BCCNS

#### Other potential cancer applications

Skin, osteosarcoma, lung, ovarian and prostate

Source: IMS Health, MAT February 2017.



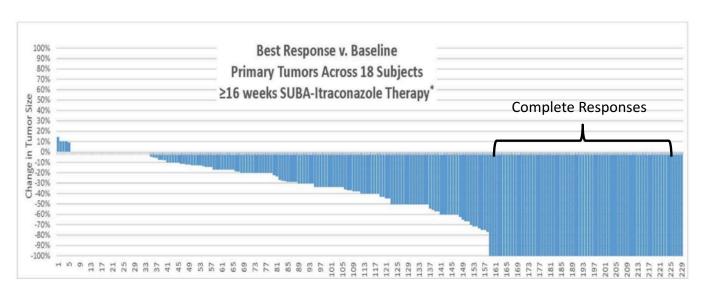
## ...and achieved strong results from Phase IIb Study in BCCNS

#### Indication

- High unmet clinical need in patients with BCCNS with standard of care being surgical excision
- Annual US population estimates for BCCNS (Gorlin) ~10,000

Interim results

- Independent analysis of the target lesions reported that:
- 31% of target lesions studied demonstrated a complete response
- An additional 30% of target lesions demonstrated a 30% or greater reduction in size



#### **Next steps**

- Expect to complete Phase IIb trial in 2017
- A meeting with FDA is planned to discuss results



### Key takeaways - R&D

Targeting 6
launches in 2017
with >US\$500m
in IMS sales

Greater
investment in
early stage brand
programs and
complex generic
programs

Selective strategic alliances to broaden capability set

Pipeline
expansion
through internal
development, codevelopment and
acquisition



Corporate & Business Development

Peter Paltoglou



### **Corporate & Business Development overview**





# Focused corporate strategy with defined playbook to build scale and capability across key business units

#### CORE

#### Generic

 Complex technology e.g. potent and modified release

#### **Branded**

Therapeutic focus

 e.g. dermatology and
 infectious disease

#### **EXPANSION**

## Leverage partners technologies

 Alternative dosage forms e.g. transdermal and topical

Other niche business development opportunities

#### **STEP-OUT**

Consider adjacent opportunities selectively

#### **BOLT-ON**

Consider small enterprise or product opportunities

Licensing and partnering opportunities

**M&A** opportunities



## **Current corporate trends greatly shaping Mayne Pharma's strategic agenda**

#### Trends over the past years...

### Mega-deals created scaled organisations





### ...is driving prevailing corporate activity

Poor performance has led to mgmt change

Companies have undertaken strategic reviews leading to reorganisations and asset disposals to release capital and to focus on:

- Core therapeutic areas
- Pipeline and high growth products \\_\_VALEANT



#### Acquisitions financed by large amounts of debt1

Endo and Par US\$8.05bn acquisition Impax and Teva
US\$586mn acquisition

**Teva and Allergan** US\$40.5bn acquisition







52% debt funded

65% debt funded

100% debt funded

**Limited acquisitions** expected by US firms in the near term due to **stretched balance sheets** 

Industry headwinds impacted profitability leading to high leverage levels and depressed valuations



Corporate tax reform may accelerate M&A amongst US peers in the medium – long term

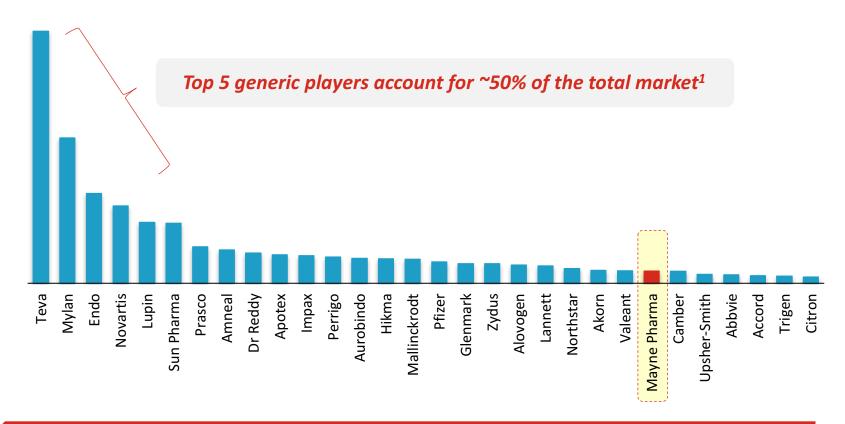
Opportunities for well-funded, focused companies to take advantage of more efficient valuations and ongoing pressure to divest assets



## Fragmented generics market provides opportunity for growth

#### **Top 30 US Generics players**

(Sales US\$m)



The US generics market remains open to further consolidation activity and Mayne Pharma is well positioned to participate across multiple dimensions



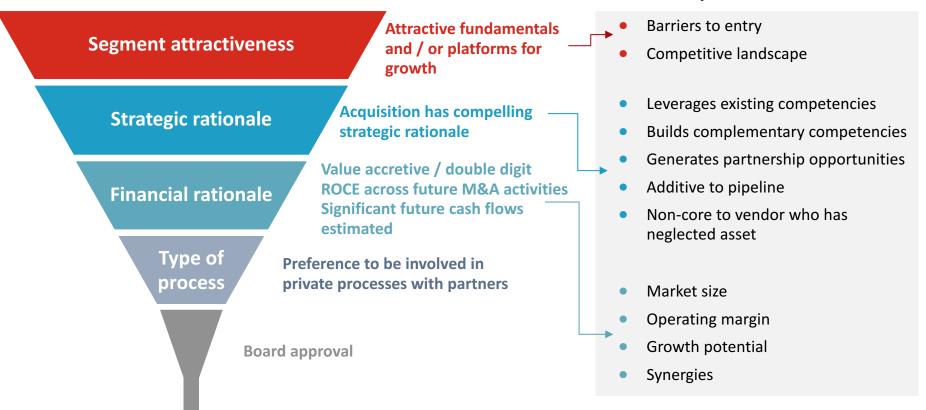
## **Corporate & Business Development drivers of success**





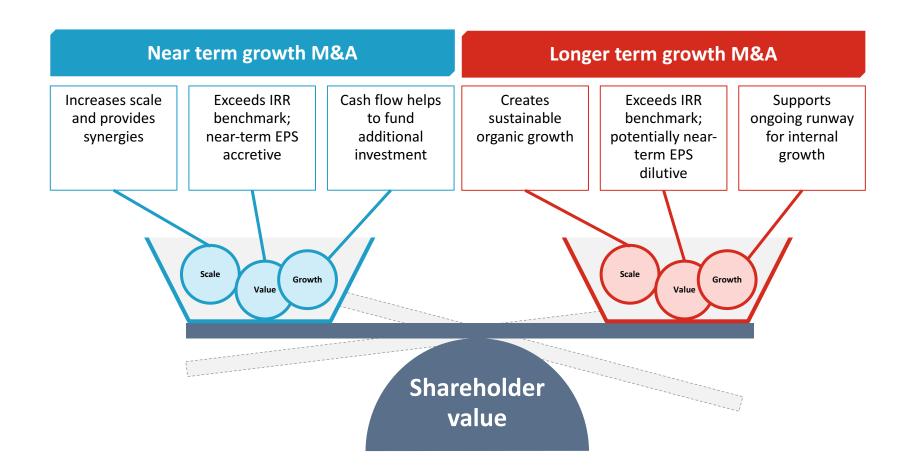
## Mayne Pharma's filtering process for new opportunities

#### **Specific criteria**





## Creating a balanced approach to drive long-term shareholder value





### In-licensing and partnering frameworks

JM⊗ Johnson Matthey

#### **Dofetilide**

- Entered into a partnership to share the costs of development and profits equally from the sale of dofetilide capsules
- Johnson Matthey developed a non-infringing API
- Became Mayne Pharma's first first-to-file Paragraph IV opportunity
- Has become the largest selling generic product

#### Corium

#### **Fentanyl TDS**

- Acquired ANDA for fentanyl reservoir patch from Par Pharma and assumed the manufacturing and supply agreement with Corium
- Profit share model
- Flexible approach to structure of commercial arrangements to reflect risk and preferred approach for Corium and Mayne Pharma

#### mithra PHARMAGEUTICALS

#### Myring<sup>®</sup>

- Long-term exclusive license and supply agreement with Mithra for Myring<sup>®</sup>
- Milestone payments of at least €10.0m are to be paid following ANDA approval and commercial launch
- Key economics and deal terms will vary based prevailing competitive dynamics at the time

The deal structure varies per transaction, depending on the economics, partnership agreement and product being acquired



### Track record for delivering 'on strategy' and value accretive transactions for shareholders



#### **Metrics acquisition**

- Provided US operating platform
- Acquired contract services business and niche generic portfolio



- **Expanded commercial capability**
- Created new relationships with CMOs and development organisations



Doryx<sup>®</sup> acquisition

 Created new specialty brands platform



#### Teva portfolio acquisition

- Increased scale and growth opportunities for generic business
- Create new product in-licensing opportunities
- Pipeline of products to drive future growth

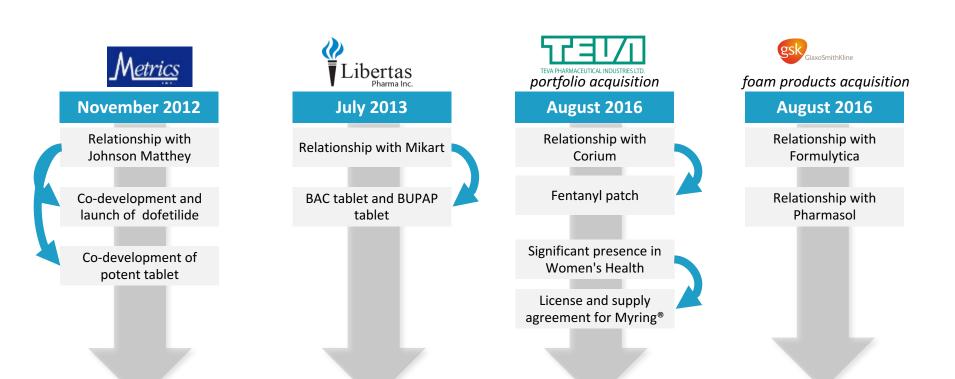


#### **gsk**<sub>GlaxoSmithKline</sub> **GSK foam products acquisition**

- Clinically differentiated patent protected products
- Access to new complex technology platform to leverage in future development programs



## Track record for establishing series of successful strategic alliances from recent M&A activities



#### **Key commercial partners**











Crystallising relationships with new partners with aligned interests through our pragmatic, commercial approach



## Leveraging M&A to establish new business pathways

GSK foam product acquisition illustrates Mayne Pharma ability to create a completely integrated business targeting high value product opportunities





Project selection incorporating scientific, IP, regulatory and commercial



Strategic partnership for medical dermatology providing formulation development expertise for product candidates



Strategic partnership developed to provide complete supply and tech transfer solution for future foam products



Specialty Brands to manage all commercial activities including sales, promotion, KOL / advisory boards and patient support

All transactions scrutinised to identify new and complementary business opportunities that fit with our underlying capabilities and strategic focus



## Key takeaways – Corporate & Business Development

Partnerships and alliances play a key role in adding technologies and capabilities

M&A is a core platform for growth

Targeting double digit return on capital employed across future M&A activities

Opportunities available for well-funded players



## 8 Closing Remarks

Scott Richards



### **Operational Update and Earnings Outlook**

- Tougher generics pricing environment in 2H17 which is expected to result in FY17 Teva portfolio generic sales below original guidance
- Teva portfolio gross profit margins tracking ahead of 50% guidance and EBITDA is broadly in line
- Upsides will include further FDA approvals and market share gains. Potential first-to-market opportunity on a US\$250m product which has been granted expedited review
- SBD expected to have a significantly stronger 2H17 versus 2H16 following the launch of Fabior® and Sorilux® foams
- Metrics Contract Services is expected to continue to deliver strong double digit growth in FY17
- Positive operating cashflow in 3Q17 which is expected to continue increasing over the 2H17



### Final takeaways – our strategic pillars....





## ...to drive our 2021 strategic ambitions















- Triple size of the business in revenue terms to >A\$1.5bn
- Double digit CAGR EPS growth
- R&D investment to return to ~8-10% of group revenue
- New products to drive revenue and earnings growth (US\$7bn pipeline¹)
- Business development to supplement organic growth

Underpinned by fundamental growth and operational platforms

**R&D** pipeline

**M&A** execution

Scale and efficiency across operating segments

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A specialty pharmaceutical company with an increasingly diversified portfolio of products, technologies and footprint