

# **Mayne Pharma Group Limited**

Goldman Sachs
Emerging Companies Conference
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#### Glossary

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



#### **Group snapshot**

#### Mayne Pharma's focus

Affordable and effective medicines sourced and distributed efficiently

Therapeutically focused expansion of product portfolio via R&D and business development

Quality contract services and manufacturing

A\$530m revenue in FY18

70+ marketed products

1.2b doses sold in Australia and US in 2018



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

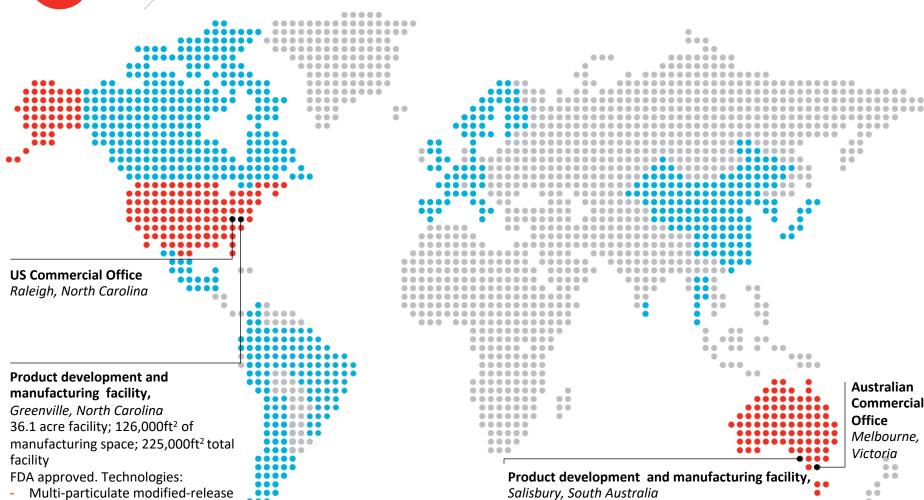
950 employees

A\$40m+ invested in R&D in FY18

- Direct commercial presence
- Indirect presence through distribution partners for current and pipeline products
- Office and/or manufacturing facility

### mayne pharma

#### Mayne Pharma's international footprint



beads / tablets

- Potent drug handling
- Controlled substances (CII-CV)

Salisbury, South Australia

32.1 acre facility; 129,000ft<sup>2</sup> of manufacturing space. FDA, MHRA and TGA approved. Technologies:

- Multi-particulate modified-release beads / tablets
- Potent drug handling
- Microencapsulation utilising spray drying process
- Semi-solids and liquids

Direct commercial presence

Indirect presence through distribution partners for current and pipeline products



### Mayne Pharma's operating platform has been transformed by M&A, R&D and other commercial initiatives

M&A activity

## R&D activity

Nov 2012
Acquisition of
Metrics, Inc. for
US\$115m

May 2015
US\$50m
acquisition of
DORYX® assets
from Actavis

Aug 2016
US\$652m
acquisition of US
product portfolio
from Teva and
Allergan

Aug 2016
U\$\$50m
acquisition of
FABIOR® and
SORILUX® foam
products from GSK

Jul 2018
Acquisition of generic EFUDEX®

Oct 2018
Acquisition of
LEXETTE™
(halobetasol foam)

Jul 2013
Launched generic doxycycline DR tablets and erythromycin DR

capsules in the US

Jun 2016 Launched dofetilide capsules in the US, first Gx to Pfizer's TIKOSYN® Jul 2016 A\$26m settlement received on patent litigation with Forest Laboratories

Aug 2016
Launched DORYX®
MPC in the US,
new formulation of
doxycycline

Jun 2017
Launched
doxycycline IR
tablet in the US,
first generic to
Almirall's
ACTICLATE®

Dec 2018

TOLSURA™
(SUBA®itraconazole)
approved by FDA
for systemic
infections

2012

2013

2014

2015

2016

2017

2018

Commercial

Feb 2015
Established
Specialty Brands
platform with 60
sales reps following
acquisition of

DORYX®

Dec 2017

Expanded Specialty Brands sales team to 115 sales reps to accelerate growth of the dermatology brands Jan 2018

Brought in house the manufacture of amiodarone tablets and launched liothyronine tablets Mar 2018

Completed US\$25m expansion of solid oral dose facility in Salisbury, AU Apr 2018

New US\$80m solid oral dose manufacturing facility opened in Greenville, US Jun 2018
Received first
commercial
manufacturing
revenues from a
full service MCS
client



#### Mayne Pharma business units

#### **US Business Units**

#### **Generic Products Division** (GPD)

- Develops, markets and distributes generic products in the US
- Focused on developing and bringing to market complex generic products

#### **Specialty Brands Division** (SBD)

- Develops, markets and distributes specialty branded products in the US
- Focused on clinically differentiated products with therapeutic value in dermatology, infectious disease and rare diseases

#### **Metrics Contract Services** (MCS)

- Provides contract pharmaceutical development. manufacturing and analytical services to third party customers globally
- Focused on niche and scientifically challenging areas

Oral solid dose development through to commercial supply,

First-in-human CTM, PI, PII, PIII

Stability and ongoing release

including potent handling

Method development &

validation

#### **Rest of World**

#### **Mayne Pharma** International (MPI)

- Develops, markets and distributes branded products globally (excl. US)
- Focused on in-licensing and out-licensing specialty brands
- Provides contract pharmaceutical development and manufacturing services

#### MONUROL® (fosfomycin)

- UROREC® (silodosin)
- ASTRIX® (aspirin)
- DORYX® (doxycycline)
- KAPANOL® (morphine)
- LOZANOC® (SUBA® itraconazole)
- OTC / injectables

#### Potent compounds (dofetilide, liothyronine, fluorouracil)

- Modified-release products (budesonide, doxycycline, erythromycin)
- Hormonals (oral contraceptives)

business

60+ marketed products

Top 25 US retail generics

contraceptives in the US

Top 3 supplier of oral

 Multi-channel product distribution strategy

competitors

- SORILUX® (calcipotriene)
- FABIOR® (tazarotene)
- DORYX® MPC (doxycycline)
- LEXETTE™ (halobetasol)
- TOLSURA™ (SUBA®itraconazole)
- Pipeline of rare disease programs (trifarotene and SUBA®-itraconazole)
- Top 20 US dermatology company
- 115 person dermatology sales team
- 15 person institutional field team
- 60% of portfolio have 3 or less Gx Multi-channel product distribution strategy

- 25 years of history in contract services
- 100+ 3<sup>rd</sup> party clients
- Supported by 150+ analytical chemists and formulators
- 150 years of history in Australian market
- 20+ 3<sup>rd</sup> party clients
- 11 person specialty sales team detailing urology, infectious disease, GPs and other specialists

### **KEY PRODUCTS &** SERVICES

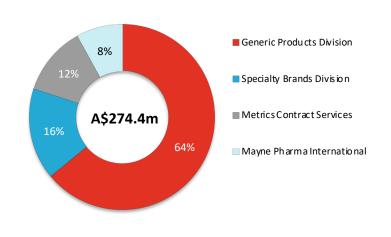
**OVERVIEW** 

# **KEY FEATURES**

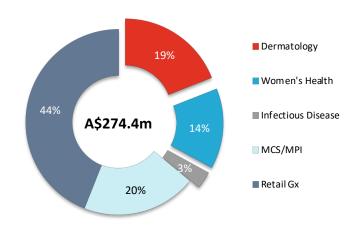


### Actively rebalancing the portfolio toward sustainable therapeutic areas and channels

#### 1H19 revenue by segment



#### 1H19 revenue by category

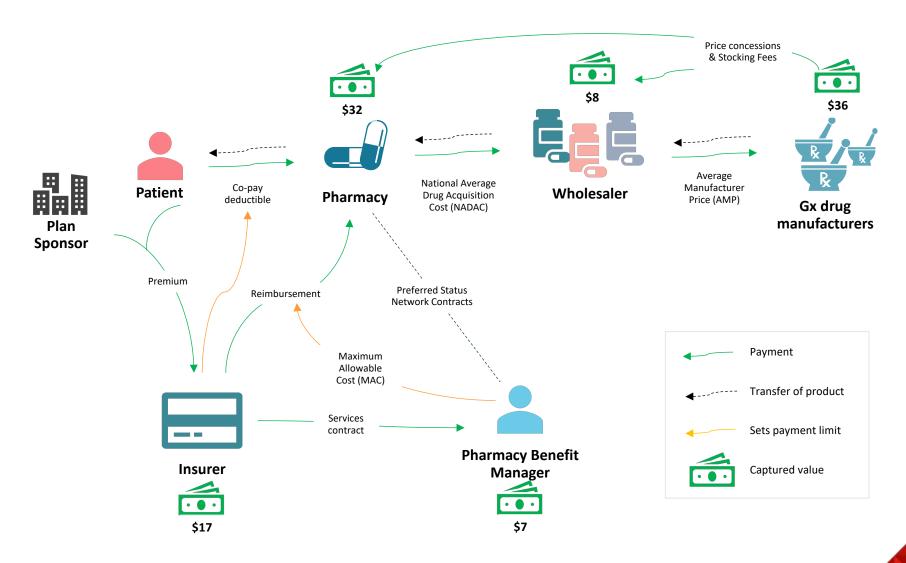


- Development pipeline focused on expanding portfolio within these therapeutic platforms
  - >75% of 1HFY19 R&D spend directed to key therapeutic categories of dermatology, women's health and infectious disease
- Acquisitions and licensing activity focused on these therapeutic platforms
  - LEXETTE™ foam and generic EFUDEX® cream are dermatology products
  - Actively targeting further complementary dermatology, women's health and infectious disease products
- MCS and MPI provide further diversification and sustainability of earnings and are well positioned for further growth



#### **Understanding the US value chain...**

Generic industry – spread of \$100 across value chain

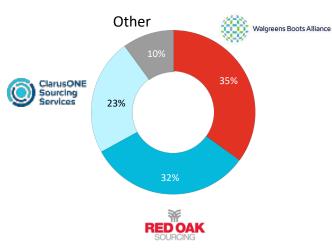




#### Multi-channel strategy to drive growth

#### Retail customer segmentation

Estimated US generics market mix



#### **Channel consolidation / partnerships**



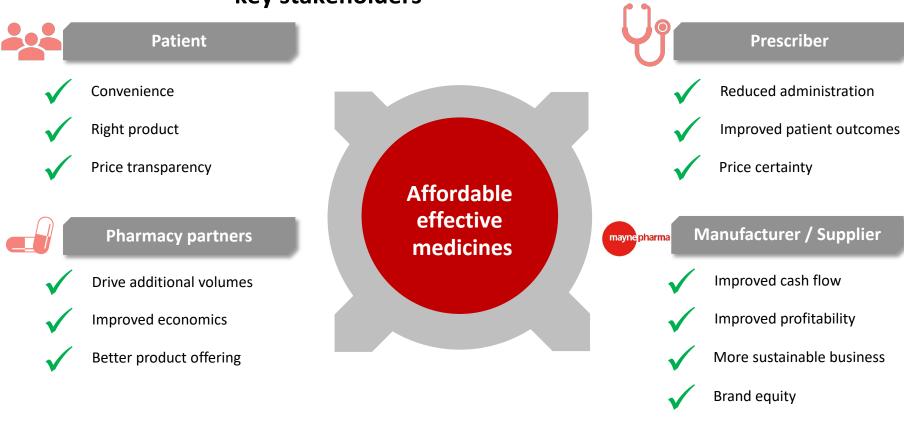
Major Retail / Wholesale channel Secondary Retail / Wholesale channel

Government channel

Specialty pharmacy channel



Channel strategy built around leveraging commercial infrastructure to create a more seamless experience for key stakeholders



Blended promotional team (in-field, tele-sales)

**Broad product portfolio** 

**National pharmacy network** 

Focused prescriber base

Aligned managed care coverage

**Omni-channel fulfilment** 



### Mayne Pharma has a unique and differentiated dermatology platform...

- Mayne Pharma has a differentiated dermatology portfolio with an established front end commercial platform
  - 4 patent protected dermatology brands and 5x multisource/generic products
  - 115 sales reps
  - Multi-channel distribution including B2B, government, specialty pharma
  - Top 20 US topical dermatology company<sup>1</sup>
- Dermatology is Mayne Pharma's largest therapeutic category with a unique distribution profile
  - Significant business in alternate channels
  - Gross margin >80%
- Strong shares in key product markets<sup>2</sup>
  - 61% share of DORYX® market
  - 39% share of ACTICLATE® market
  - 28% share of EFUDEX® market
- Key strategic priorities
  - Improve sales force effectiveness
  - Broaden pipeline and continue to drive patient / physician centric offerings
  - Leverage women's health portfolio in dermatology

#### Mayne Pharma dermatology portfolio by key skin diseases

Skin disease	US Patient prevalence <sup>3</sup> (millions)	Branded	Generic	
Actinic keratosis	58		Gx EFUDEX®	
Acne	50	(tazarotene) Foam, 0.1%  Dorryx®MPC  (Dusyysfine Hydate Debystol Actions Tables)  120 mg	Gx DORYX® Gx ACTICLATE® Gx MONODOX®	
Atopic dermatitis	28		Gx LIDEX®	
Psoriasis	8	(halobetasol propionate) Topical Foam, 0.05%  Sorilux (calcipotriene) Foam, 0.005%		

<sup>(1)</sup> IQVIA NSP Sales, Dec 2018, topical dermatologicals

<sup>(2)</sup> IQVIA, weekly TRx, 22 Mar 2019. Excludes B2B business. DORYX® includes Mayne Pharma brands and generics

<sup>(3)</sup> American Academy of Dermatology; Skin Cancer Foundation; National Eczema Foundation; Epidemiology of Chronic Pruritus: Where have we been and where are we going?



### ...with two dermatology orphan disease programs in development

#### SUBA®-itraconazole in BCCNS

- SUBA®-itraconazole is being repurposed as a potential anti-cancer treatment in Basal Cell Carcinoma Nevus Syndrome (BCCNS) - commonly known as Gorlin's Syndrome
- FDA and EMA granted Orphan Drug Designation for BCCNS
- Mayne Pharma assumed US commercial rights and full control of the BCCNS program from HedgePath in December 2018
- Phase II(b) clinical trial in 38 BCCNS patients completed showing majority of target lesions decreased in size and SUBA®-itraconazole was well tolerated
- Global Phase III multi-center clinical trial planned to commence in CY19
- Global market potential: US\$300m<sup>1</sup>
- Formulation and method of use patents with expiries ranging from 2023 to 2035

#### Trifarotene in rare skin diseases

- Trifarotene is a new chemical entity under Phase II development for congenital ichthyosis
- Galderma retains rights to common dermatology indications (acne, psoriasis)
- FDA granted Orphan Drug Designation for this indication
- IND approved by FDA in January 2019
- Phase II dose finding study to commence in CY19
- Current treatments are emollients with body wraps, topical and oral retinoids (off label)
- Molecule has potential application in a number of other rare diseases such as BCCNS and T-cell lymphoma
- Global market potential: US\$200m<sup>1</sup>
- NCE and formulation patent applications with expiries ranging from 2025 to 2033

Both programs will leverage Mayne Pharma's dermatology capabilities and raise profile in serious disease states and offer global expansion opportunity



#### **Broad Women's Health portfolio covering physician needs**

- Mayne Pharma has an extensive women's health portfolio focused on contraceptives
  - 18 branded generic and 3 generic products
  - 3<sup>rd</sup> largest supplier of oral contraceptives in the US
  - Pipeline includes the largest contraceptive product sold in the US - generic NUVARING®
  - Current marketed portfolio covers 48% of OB-GYN oral contraceptive prescriptions
  - Multi-channel distribution including tele sales, B2B, government, specialty pharmacy
- Market a number of oral contraceptives with an acne indication prescribed by dermatologists e.g. ZARAH®, TILIA® FE
- Key strategic priorities
  - expand channels to market
  - optimise supply network to improve manufacturing costs
  - addition of complementary branded products and establishing a direct sales team

#### Mayne Pharma contraceptive portfolio

Type of contraceptive	Market TRx <sup>1</sup> (millions)	Mayne Pharma's marketed products
Monophasic (same hormone throughout cycle)	45	LEVORA® LOW-OGESTREL® LUTERA® MICROGESTIN® MICROGESTIN® FE NECON® SRONYX® ZARAH® ZOVIA®
Multiphasic (different level of hormones throughout cycle)	14	CAZIANT® TRIVORA® LEENA® TILIA® FE
Extended cycle (limit period to every 3 months)	2	AMETHIA® AMETHIA® LO Gx QUARTETTE®
Shortened hormone- free interval	13	AZURETTE®
Progestin only	5	CAMILA® ERRIN®
Ring	4	

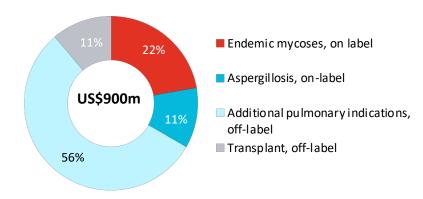
(1) IQVIA TRx, Dec 2018



### Launch of TOLSURA™ establishes a new Infectious Disease / Pulmonology platform

- Launch of TOLSURA™ (SUBA®-itraconazole) has enabled Mayne Pharma to establish a new infectious disease / pulmonology platform
  - TOLSURA™ is a new formulation of itraconazole indicated for the treatment of certain systemic fungal infections in adult patients
  - Specialised experienced field team of 15 (averaging 18+ years of hospital experience)
- Creates new institutional / hospital sales capability
- US addressable market: US\$200m endemic mycoses
- Key strategic priorities
  - Successful launch of TOLSURA™
  - Broaden therapeutic use of TOLSURA™ through further clinical programs to access other markets (US\$900m addressable market including pulmonary indications / prophylaxis in transplant patients)
  - Expand product portfolio in channel
  - International expansion following US approval

#### Potential expanded addressable market



#### Treated patients per annum

(US patients)

Condition	Estimate of US Infection rate / treated patients <sup>1</sup>	TOLSURA Label	IDSA Practice Guidelines <sup>2</sup>	
Blastomycosis	6,000	<b>√</b>	✓	
Histoplasmosis	10,000-20,000	<b>√</b>	✓	
Coccidioidomycosis	10,000-25,000		✓	
Lung transplant	2,000		✓	
Bone marrow transplant	20,000		✓	
Refractory aspergillosis	300,000-350,000	✓	✓	
Fungal asthma	500,000-750,000		✓	



### New Gx competitive pressure on dofetilide, liothyronine and BAC capsule

Product	IQVIA product market size (US\$m)	# of Gx approvals	New Gx launches in CY19	Change in product TRx market share since 31 Dec 18	nare product market	
<b>Dofetilide capsule</b> (Gx TIKOSYN®)	135	6	2	-8%	35%¹	
<b>Liothyronine tablet</b> (Gx CYTOMEL®)	105	5	1	-	44%	
Methylphenidate ER capsule (Gx RITALIN LA®)	80	2	-	-	41%	
<b>Doxycycline tablet</b> (Gx ACTICLATE®)	70	3	-	+11%	39%²	
Fluorouracil cream (Gx EFUDEX®)	55	2	-	+2%	28%	
Butalbital / APAP / Caffeine capsule	30	2	1	-10%	90%	

Source: IQVIA, Sales data, Dec 2019 and IQVIA TRx data, 22 Mar 2019 Gx – Generic competitor

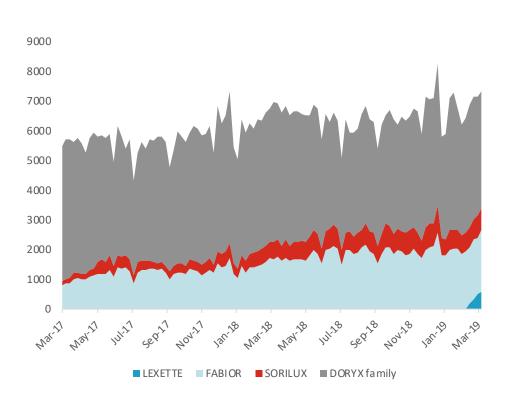
<sup>(1)</sup> Includes Northstar which Mayne Pharma also manufacturers

<sup>(2)</sup> Excludes B2B business



#### Dermatology sales team driving prescription growth

#### **Dermatology Weekly TRx (prescriptions)**



Average weekly TRx	1Q CY19	1Q CY18	1QCY19 v 1QCY18
DORYX® franchise	4,024	4,390	(8%)
FABIOR®	2,009	1,503	34%
SORILUX®	673	495	36%
LEXETTE™	459	-	-
Total TRx	7,165	6,388	12%
DORYX® 200mg AG	1,352	889	52%

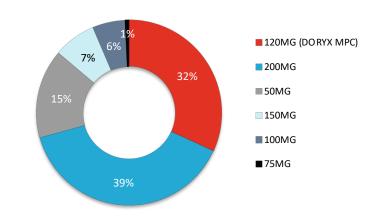
Source: IQVIA, weekly TRx, 22 Mar 2019



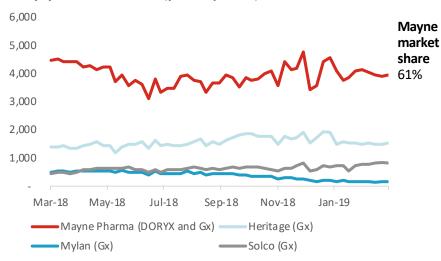
#### DORYX® remains a key specialty franchise

- Mayne Pharma has retained 60% share of doxycycline DR TRx
- DORYX® franchise continues to outperform from new formulations and favourable product sales mix
- Settlement of DORYX® MPC patent litigation with generic filers Teva and Lupin during 1HFY19
- DORYX® volumes holding steady despite launch of novel tetracycline - SEYSARA®

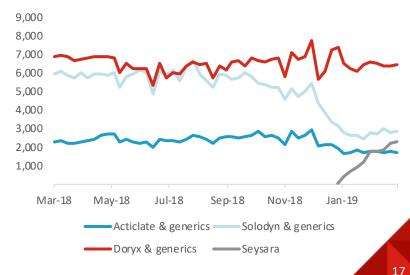
#### **DORYX®** franchise mix (prescriptions)



#### **Doxycycline DR market (prescriptions)**



#### Oral antibiotic acne market (prescriptions)

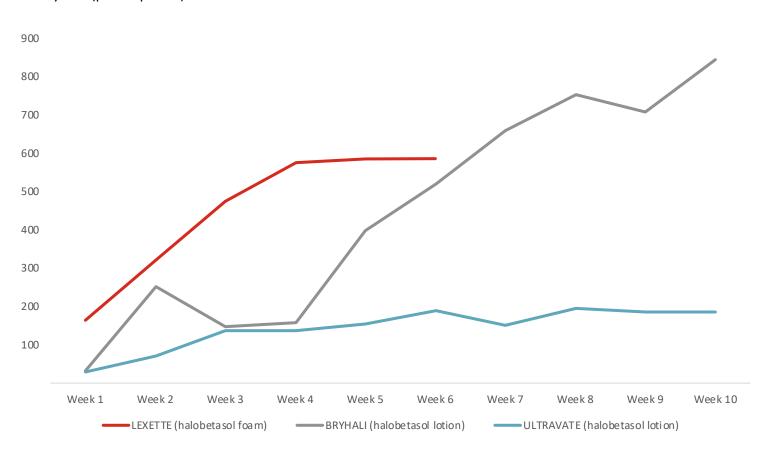


Source: IQVIA, weekly TRx, 22 Mar 2019



### **LEXETTE™** (halobetasol) launch gaining significant prescriber adoption

#### Comparison of LEXETTE™ and other recent branded halobetasol launches Weekly TRx (prescriptions)



Source: IQVIA, weekly TRx from launch

18



#### Development pipeline expected to drive future growth

#### Select late stage pipeline projects

Product / formulation	Indication	Mkt size (US\$m)¹	Bx / Gx	No. Gx competitors	Formulation development	Pre- clinical	Phase II	Phase III	Filed FDA
SUBA®- itraconazole	BCCNS	300	Вх	-				-	
Trifarotene	Congenital Ichthyosis	200	Вх	-			•		
Gx NUVARING	Contraceptive	930	Gx	0					-
Gx FENTORA	Pain	65	Gx	0					-
Gx patch	Motion sickness	140	Gx	1					-

Continue to bolster pipeline through business development activity in key therapeutic areas



#### Our key strategic priorities to drive sustainable future growth

Therapeutically focused expansion of product portfolio



- Developing and sourcing products aligned to key therapeutic categories
- Multi-source dermatology offering to align with differentiated commercial capabilities
- Broaden women's health and infectious disease portfolio

High quality reliable supply



- Optimise manufacturing network to drive cost efficiencies and flexibility
- Sourcing and supply chain activities to support product market priorities
- Concept-tocommercialisation offering for MCS clients

Multi-channel, agile commercial model



- Maximise value of existing on market portfolio
- Focused on getting 'closer to the patient'
- Multi-channel distribution
- Develop commercial infrastructure to support women's health

# Keeping our promises to patients, for better medicines and a better tomorrow

