



Mayne Pharma Group Limited

Company presentation
UBS Australasia Investor Conference
November 2016





Mayne Pharma is a specialty pharma business with diversified operations across the value chain

Markets served by Mayne Pharma



Generic Products

Develops, manufactures and distributes generic products



Specialty Brands

Develops, manufactures, markets and distributes specialty branded products



Contract Services

Provides contract pharmaceutical development and analytical services to third party customers globally



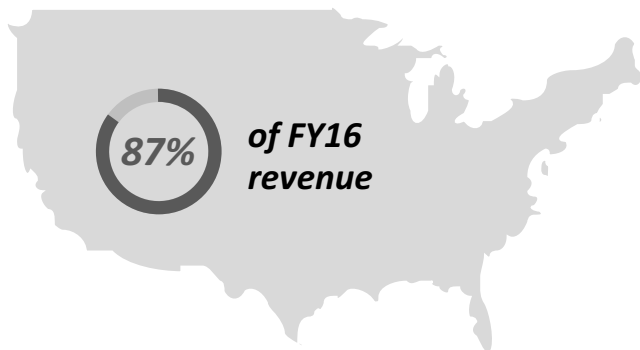
High barrier to entry, specialised known molecules that bring therapeutic value to patients
(complex oral dose forms, highly potent compounds, modified release products)



Quality contract services and manufacturing to third parties



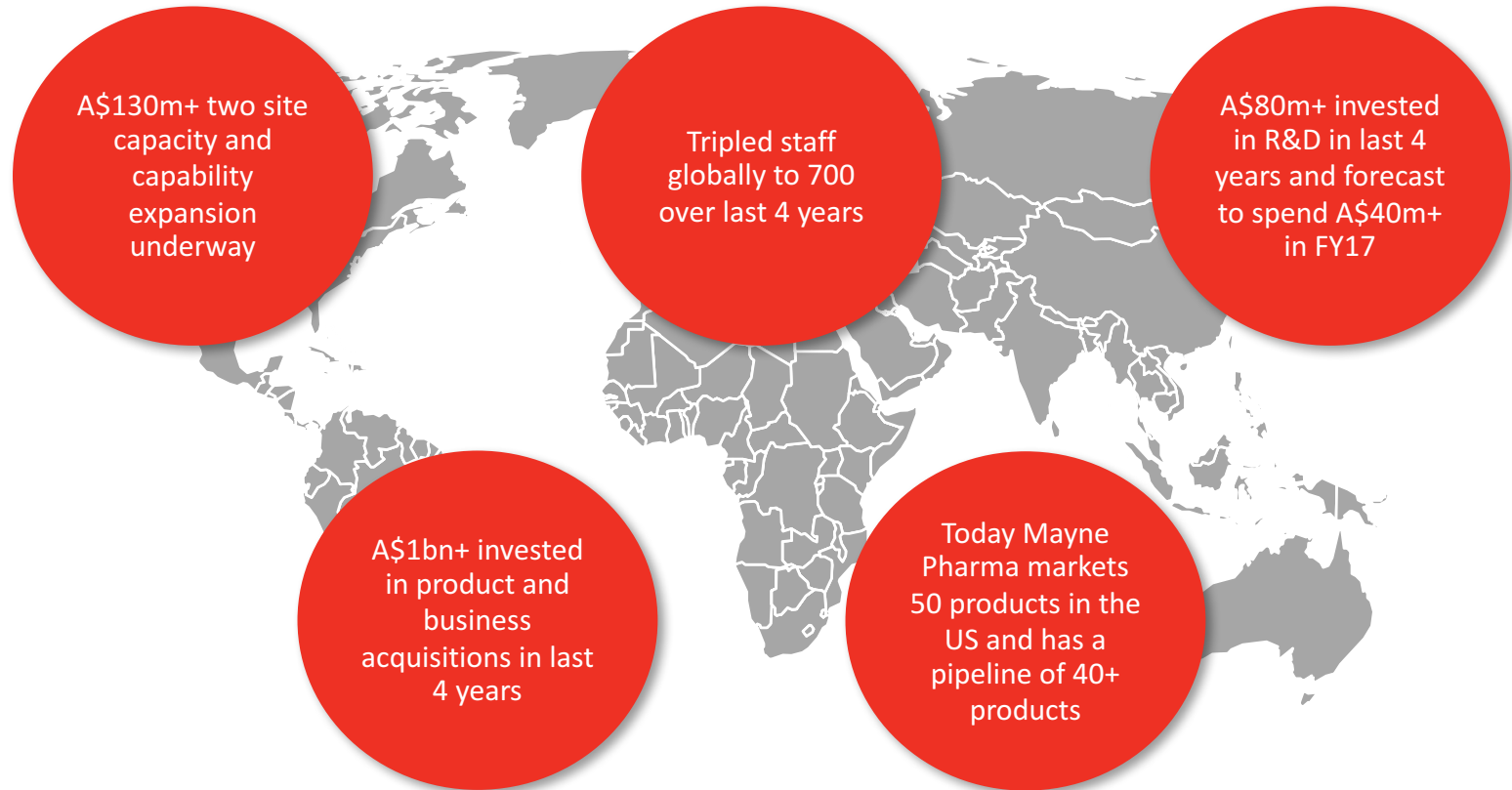
Underpinned by expertise in drug delivery technology



Mayne Pharma key products and services

	US Business Units			Rest of world
	Generic Products	Specialty Brands	Contract Services	Mayne Pharma International
Description	Develops, manufactures, markets and distributes generic products in the US	Develops, manufactures, markets and distributes specialty branded products in the US	Provides contract pharmaceutical development and analytical services to third party customers globally	Develops, manufactures, markets and distributes branded and generic products globally (excl. US)
Strategy	<ul style="list-style-type: none"> Focus on developing high barrier to entry products Optimise market penetration of product portfolio Rapidly commercialise new approved products 	<ul style="list-style-type: none"> Develop and market clinically differentiated products with therapeutic value in dermatology Build new specialty therapeutic platforms 	<ul style="list-style-type: none"> Provide contract services in niche and scientifically challenging areas Globalise customer base Deliver high quality and reliable contract manufacturing 	<ul style="list-style-type: none"> Commercialise growing Australian product portfolio Build specialty brands and injectable franchise in Australia Out-license Lozanoc® and Kapanol® in new markets
Key products & services	<ul style="list-style-type: none"> Butalbital / APAP / Caffeine Carbidopa / Levodopa Clonidine Dextroamphetamine Dofetilide Liothyronine Methamphetamine Methylphenidate Oxycodone Range of oral contraceptives 	<ul style="list-style-type: none"> Doryx® Doryx® MPC Fabior® Sorilux® 	<ul style="list-style-type: none"> Analytical services (method development and validation, drug substance and drug product release, stability and trace metal analysis) Formulation Development (incl. clinical trials manufacturing) 	<ul style="list-style-type: none"> Astrix® Doryx® Eryc® Lozanoc® / Itragerm® Kapanol® / Kadian® Luxiq® Magnoplasm® Olux-E® Range of injectable products

Mayne Pharma continues to invest in its people, products, technologies and footprint



Mayne Pharma is committed to building its business globally, and investing for growth is at the core of its corporate philosophy

Investing for growth – Greenville, NC site expansion



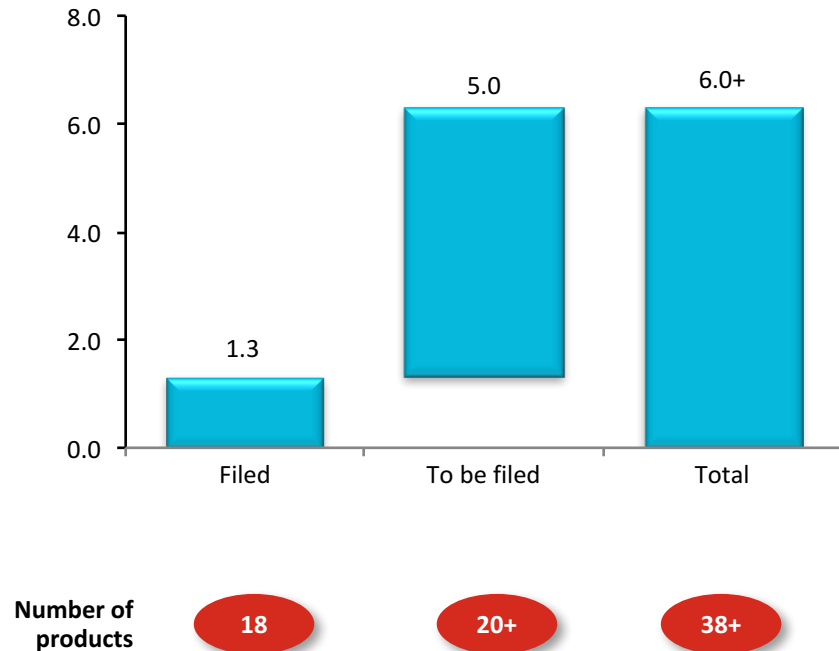
Construction status as at Sep 2016

- New 125,000ft² / 11,600m² oral solid dose manufacturing facility construction commenced October 2015
- Commercial production to migrate to new building
- Product launches remain on schedule for early 2018
- Adds multi-particulate layering, bead coating fluid bed technology, organic solvent coating capacities and handling of high potent compounds
- Increases dose capacity from 250m to over 1bn units / year

Investing for growth – research and development

- Diverse capabilities
 - Oral (tablets and capsules)
 - Topical (ointments, solutions and powders)
 - Potent compounds
 - DEA controlled substances
 - Unstable compounds
 - Modified-release
 - Products with poor bioequivalence
- Focus on higher value and high barrier to entry product opportunities in the US
- 40 pipeline products targeting US markets with annual sales >US\$6bn¹
 - 18 products pending approval targeting markets with annual sales >US\$1.3bn
- 10+ pipeline products targeting AU markets with sales > A\$100m

US Pipeline statistics – IMS market size (US\$bn)¹



1H17 highlights

Timing	Event	Country
Aug 2016	Completed acquisition of generic product portfolio from Teva and Allergan	US
Aug 2016	Acquired portfolio of foam dermatology products from GSK	US
Aug 2016	Doryx® MPC 120mg tablets launched	US
Aug 2016	Metrics Contract Services invests in new stability storage facility, tripling current capacity	US
Sep 2016	Received US\$19.6m from settlement on US patent infringement lawsuit case relating to Mayne Pharma's US Patent No. 6,194,000	US
Sep 2016	Second patent on Doryx® MPC issued	US
Sep 2016	Launched ephedrine injectable	Australia
Oct 2016	Generic to Entocort® EC (budesonide) capsules launched	US
Oct 2016	HedgePath Pharmaceuticals announced positive interim data from Phase IIb clinical trial studying the effect of Mayne Pharma's SUBA-Itraconazole oral capsules in patients with Basal Cell Carcinoma Nevus Syndrome (BCCNS) supporting the hypothesis that SUBA-Itraconazole can inhibit tumour growth	US
Nov 2016	Generic to MS Contin® (morphine sulfate) tablets launched	US
Nov 2016	Select generic products listed for sale on the US Government Federal Supply Schedule (FSS) - includes dofetilide, oxycodone/APAP, erythromycin and doxycycline	US

Teva generic product acquisition update

- Successful transition of the acquired portfolio
 - No supply chain disruptions
 - 80% of products now in Mayne Pharma labelling
- No.1 pipeline product – Budesonide extended-release capsules (generic Entocort® EC) - launched on time
- New government channel for existing Mayne Pharma products (dofetilide, erythromycin, oxycodone/APAP and doxycycline)
- Oral contraceptive portfolio providing platform for future growth
- Future: extraction of synergies
 - Cost synergies from moving products to CMOs and in-house manufacture of up to 11 products
 - Improved terms of trade will be realised over time across combined generic portfolio
 - New in-licensing / product opportunities from leveraging expanded network of API/CMO suppliers

GSK foam asset acquisition update

- On track to re-launch Fabior® and Sorilux® foam products in Q1 2017
- In-sourcing of inVentiv contract sales organisation underway, effective 1 January 2017
- Marketing campaign developed including promotional materials and sales aids
- In discussions with distribution partners for Canadian and Mexican foam products
- Acquired foam filling line which will be used to manufacture current and future pipeline foam products
 - Multiple complex and generic product development programs identified to leverage this new drug delivery platform

Doryx® franchise update

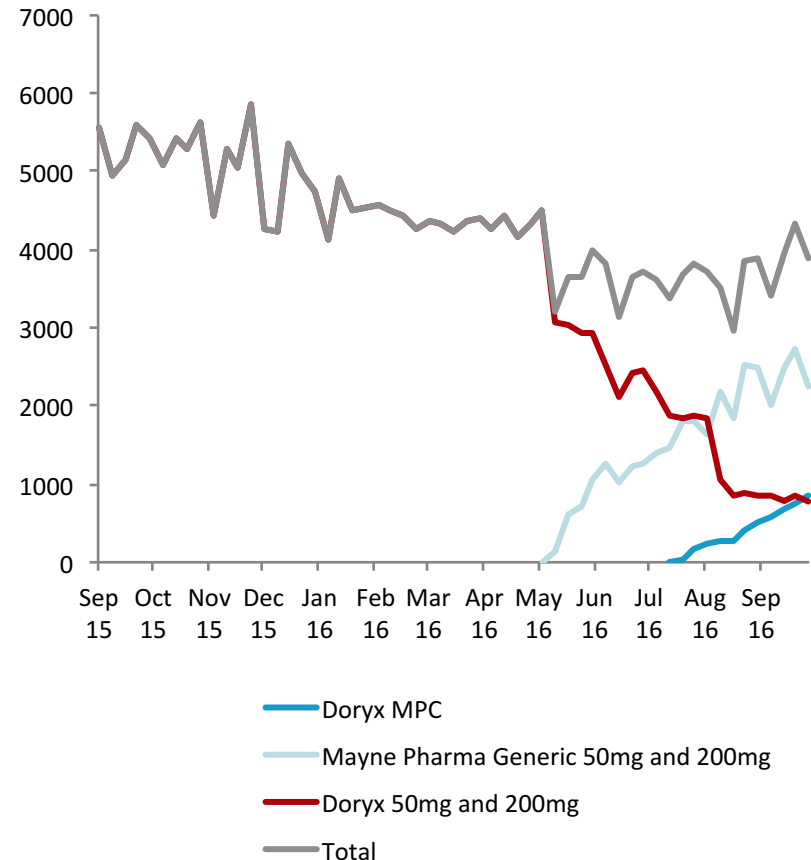
Doryx® 50mg and 200mg franchise

- Retained ~80% of doxycycline delayed-release (50mg and 200mg) market
- ~75% of Mayne Pharma (50mg and 200mg) total prescriptions (TRx's) now dispensed as generic

Doryx® MPC 120mg

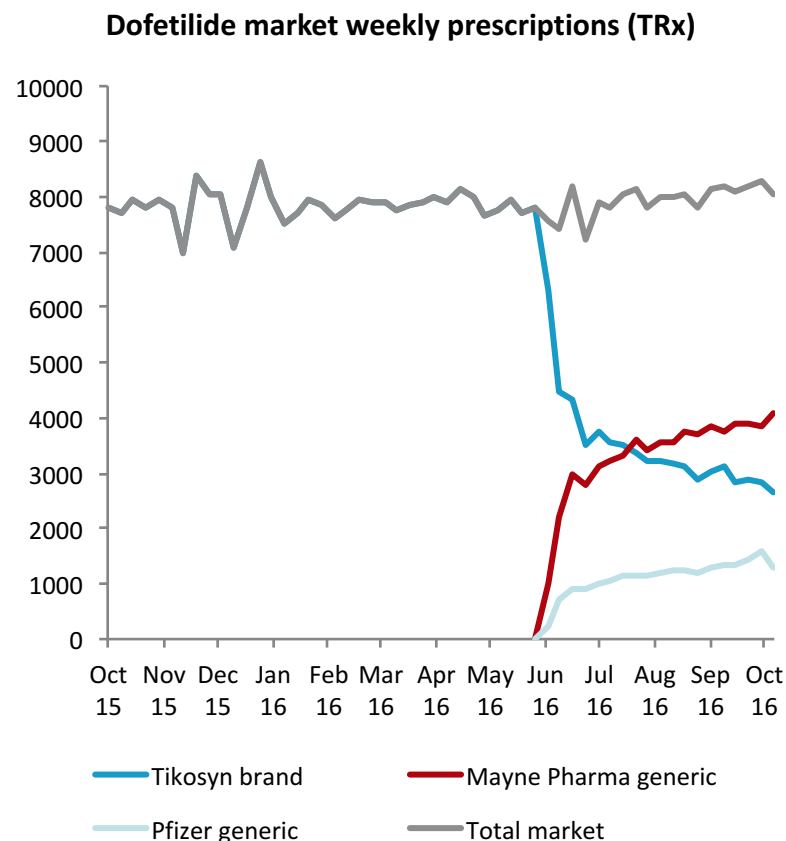
- Approved May 2016 and launched Aug 2016
- 2 Orange Book listed patents expire 2034
- New formulation incorporates a modified polymer coat designed to further retard the release of doxycycline in the acidic environment of the stomach
- 855 TRx's / week in latest data

Doryx® franchise weekly prescriptions (TRx)



Dofetilide capsules – 180 days market exclusivity

- First generic approval to Pfizer's Tikosyn® brand
- Launched dofetilide capsules on 7 June 2016 following FDA approval
- Awarded 180-days of market exclusivity as the first company to file a substantially complete ANDA containing a Paragraph IV certification
- In latest week of available prescription (TRx) data¹
 - 67% of the dofetilide market now generic and Mayne Pharma has 75% share of the generic market
 - Mayne Pharma's dofetilide has 50% share of the total dofetilide market
- IMS market size is US\$216m – up 28% on pcp²
- Expected to be Mayne Pharma's largest selling generic product in FY17



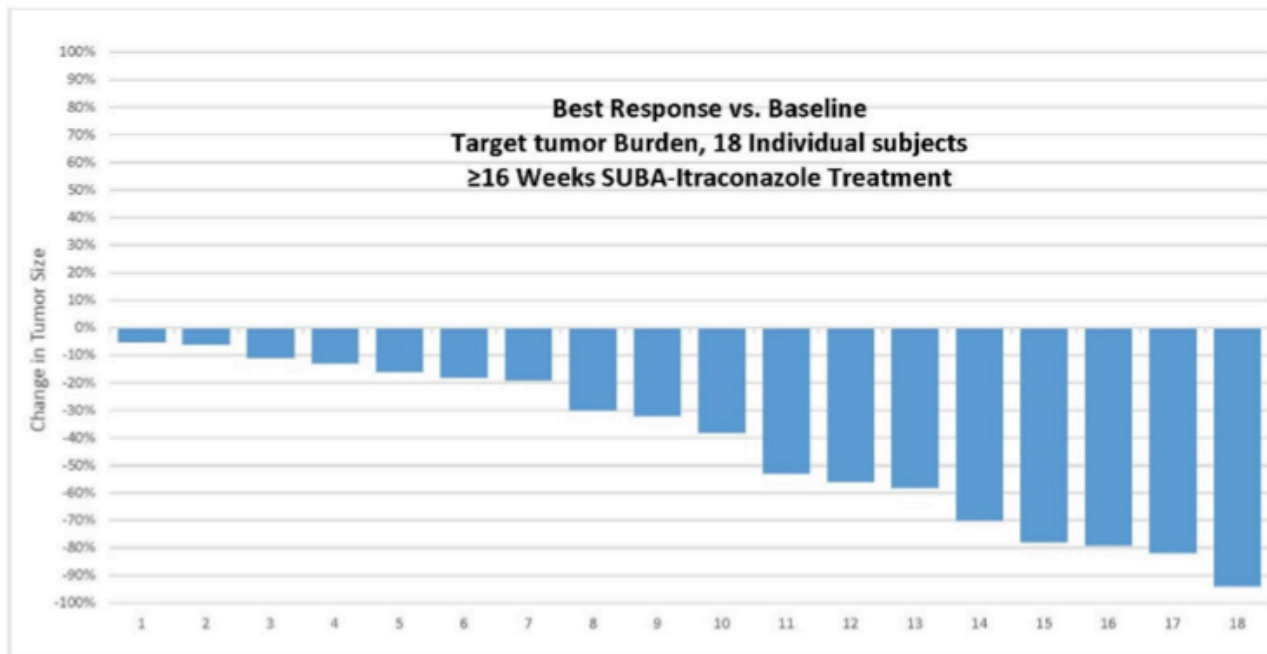
1. Symphony Health, weekly prescription data, data up to week ending 21 October 2016

2. IMS Health, MAT August 2016

Hedgepath Pharmaceuticals – repurposing itraconazole in cancer

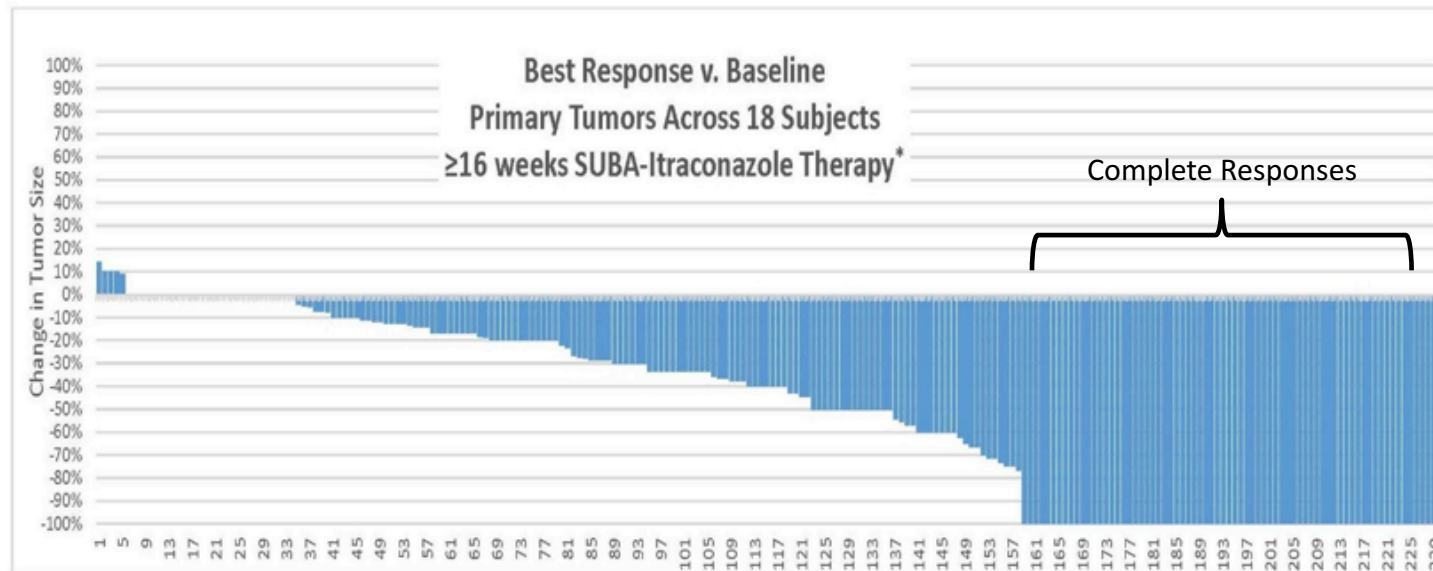
- Mayne Pharma owns 50% of Hedgepath Pharmaceuticals, a clinical stage company that is seeking to repurpose Mayne Pharma's SUBA-Itraconazole as a potential treatment in certain cancers
- John Hopkins University discovered itraconazole has anti-cancer properties based on inhibition of the Hedgehog Signaling Pathway
- 18 subjects with Basal Cell Carcinoma Nevus Syndrome (BCCNS) who had 231 surgically eligible tumours have completed 16 weeks of dosing with SUBA-Itraconazole in a US Phase IIb multi-centre clinical trial
- High unmet clinical need in patients with BCCNS with standard of care being surgical excision
- FDA granted Orphan Drug Designation in June 2016 for SUBA-Itraconazole for the treatment of patients with BCCNS
 - 7 years market exclusivity post-approval
- Seven US formulation and method of treatment patents issued with expiry dates up until 2034

Phase IIb Study of SUBA-Itraconazole in BCCNS



- Data derived from a follow-on interim analysis of results in 18 subjects who have completed 16 or more weeks of SUBA-itraconazole dosing where no subject had demonstrated an increase in target tumour burden
- The Objective Response Rate is 61.1% based on 11 of the 18 subjects exhibiting a 30% or greater reduction in target tumour burden, with a mean target tumour burden reduction of 61.2% for the 11 responding subjects

Phase IIb Study of SUBA-Itraconazole in BCCNS



- Analysis performed on the 'best response' data for 231 target lesions across the 18 subjects
- To date 141 lesions (61% of those studied) have responded to therapy with either a partial or complete response
- 229 target lesions (99% of those studied) have not progressed (meaning they have not grown more than 20% in size) with only one target lesion requiring surgical excision
- Independent analysis of the target lesions (plotted above) reported that 71 tumours (or 31% of the target lesions studied) demonstrated a complete response and an additional 70 tumours (or 30% of the target lesions studied) demonstrated a 30% or greater reduction

Significant opportunities to drive growth

1. US retail generics maximisation

- Optimise market penetration of product portfolio
- Commercialise filed FDA products
- Leverage product portfolio in non-retail segments (eg. Government, universities)
- Extract synergies from recent product acquisitions
- Efficient and reliable product sourcing, manufacturing and supply
- Portfolio expansion through growing product pipeline

2. Expand US branded specialty franchise portfolio

- Develop US specialty dermatology franchise by leveraging Doryx®, Fabior® and Sorilux® and pipeline of future products
- Build new specialty therapeutic platforms that leverage the Company's development and manufacturing capabilities

3. Optimise and grow Metrics Contract Services

- Enhance operational efficiencies and client experience
- Globalise customer base
- Introduce high value manufacturing services following Greenville, NC site expansion

4. R&D maximisation

- Portfolio selection that leverages drug delivery expertise in complex generics and specialty products
- Selective Paragraph IV filings in the US
- Development of SUBA-Itraconazole in cancer through alliance with HedgePath

5. Strategic acquisitions, licensing and partnerships

- In-licensing niche generic or specialty products in Australia and the US
- Commercialise specialty products such as Lozanoc™ through out-licensing arrangements in key markets to broaden global footprint
- Product and enterprise acquisitions with strong growth potential, complementary assets and technologies
- Build an injectable portfolio and branded specialty franchise in Australia

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

You deserve tomorrow.