Mayne Pharma Group Limited

Company Presentation
Wilson HTM Companies Conference
3 June 2014

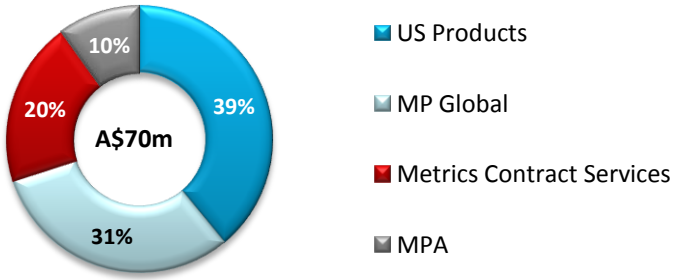


Mayne Pharma overview

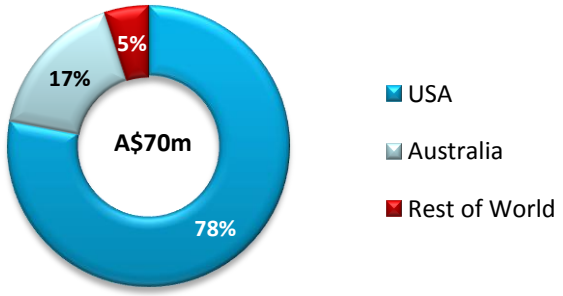
- A specialty pharmaceutical company with an increasingly diversified portfolio of products, pipeline, technologies and footprint
- Fully integrated pharmaceutical business with direct commercial presence in US and Australia
- 30-year history in drug delivery
- ~500 employees
- Vertical contract services platform offering analytical services, formulation and commercial manufacturing

1H 2014 Sales analysis

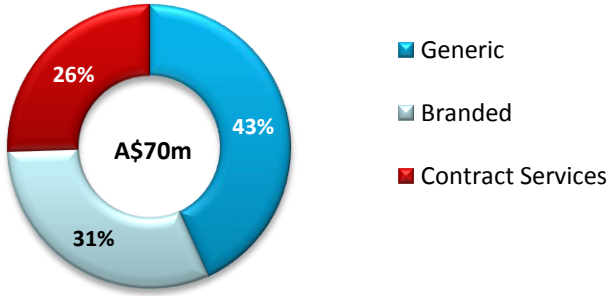
By business segment



By geography



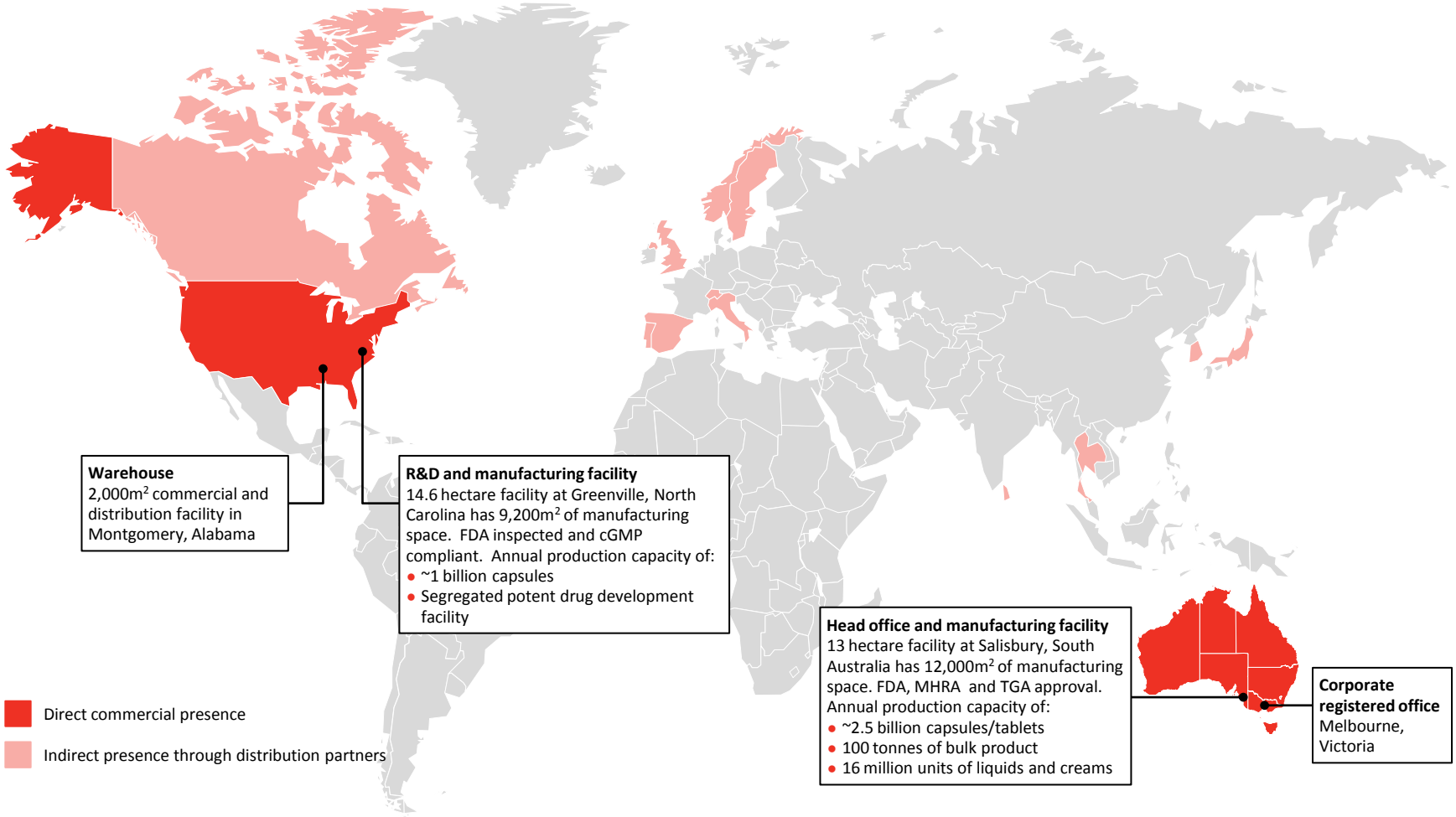
By product type



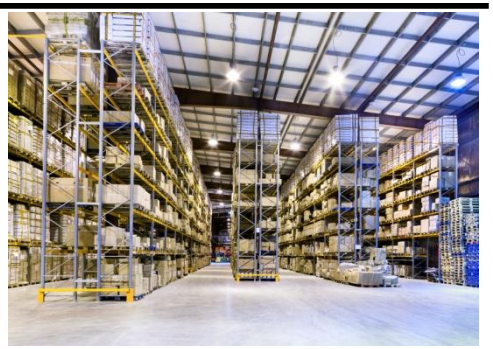
Mayne Pharma business segments

	Mayne Pharma Australia	Mayne Pharma Global	US Products	Metrics Contract Services
Overview	• Manufactures, markets & distributes branded & generic products in Australia	• Manufactures pharmaceuticals for 3rd parties globally	• Manufactures, markets & distributes branded and generic products in the US	• Provides contract pharmaceutical development services to 3rd parties globally
Key current products	• Kapanol™ • Astrix™ • Doryx ™ • Eryc™ • Magnoplasm™ • Percutane™ • Licener™ • Lozanoc™ • Doxorubicin HCl	• Doryx™ • Kapanol™/Kadian™ • Eryc™ • Astrix™ • Lozanoc™ • Commercial contract manufacturing	• Liothyronine sodium • Nystatin topical powder • Bromfenac sodium • Oxycodone HCl • Doxycycline Hyclate • Erythromycin • ZEBUTAL™, ESGIC™, LORCET™	• Analytical services • Formulation development • Clinical trial batch manufacture • Potent and cytotoxic services • Commercial contract manufacturing
Pipeline products	• 14 products filed with the TGA • 12+ further products under development		• 13 products filed with the FDA • 12+ further products under development	• n/a

Mayne Pharma's international footprint



Operating facilities

Facility location	Greenville, NC, USA	Salisbury, Australia	Montgomery, AL, USA
Location			
Inspections	FDA, MHRA inspected and cGMP compliant Last FDA inspection May 2014	FDA, TGA, MHRA inspected and cGMP compliant Last FDA inspection August 2013	FDA inspected and cGMP compliant Last FDA inspection May 2012
Technologies	High potency drug handling Matrix tablets Controlled substances (CII-CV)	Modified release beads Modified release tablets Microencapsulation utilising spray drying process	Distribute controlled substances (CIII-CV)
Scale	9,200m^2 manufacturing space	12,000m^2 manufacturing space	2,000m^2 distribution facility
Key capabilities	• Research and development • Manufacturing • Quality control and assurance • Sales and marketing • Commercial	• Corporate headquarters • Research and development • Manufacturing • Quality control and assurance • Sales and marketing • Distribution • Commercial	• Commercial operations • Distribution • Sales and marketing • Customer service

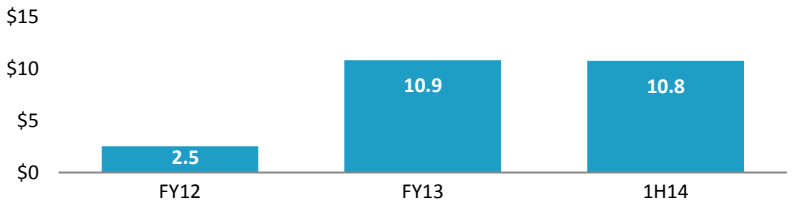
Key US on-market product portfolio

Type	Therapeutic area	Product	Form
Branded	• PAIN	• ESGIC™ • ZEBUTAL™ • LORCET™	• IR Tablet, IR capsule • IR Capsule • IR Tablet
	• DERMATOLOGY	• Doryx™ (under license to Actavis)	• DR Tablet
Generic	• PAIN	• Oxycodone HCl • Oxycodone HCl/APAP • Oxycodone HCl/aspirin • Butalbital/APAP/caffeine • Hydrocodone/APAP	• IR Tablet, IR Capsule • IR Tablet • IR Tablet • IR Capsule • IR Tablet
	• DERMATOLOGY	• Nystatin • Doxycycline Hyclate • Erythromycin	• Topical powder • DR Tablet • DR Capsule
	• OTHER	• Liothyronine sodium • Bromfenac sodium • Amiodarone • Methamphetamine	• IR Tablet • Solution • IR Tablet • IR Tablet

Growing pipeline in various stages of development

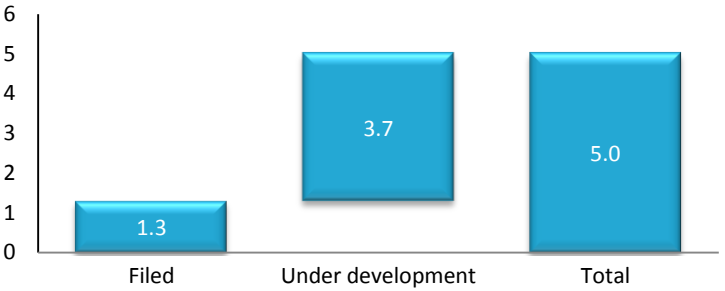
- R&D spend increased significantly over last 2 years to build US generic product portfolio
- Since 2012, R&D as a % of sales increased from 5% to 15%
- Team of 60 professionals in R&D with particular expertise in formulating complex oral dose forms including highly potent compounds, schedule II-V controlled substances, inherently unstable compounds, modified release, products with poor bioequivalence
- 25+ products under development targeting US markets with annual sales greater than US$5bn[1]:
  - 13 products now pending approval at FDA, targeting markets with >US$1.3bn[1] in annual sales
  - Expect to file 6+ products with the FDA annually
- 26+ products under development targeting Australian markets with annual sales greater than A$200m[2]:
  - 14 products now pending approval at TGA, targeting markets with >A$70m[2] in annual sales
  - Recently signed two in-licensing agreements for 6 products from Demo S.A. and Gland Pharma
  - Expect to file 6+ products with the TGA annually

R&D spend (A$m)



	FY12	FY13	1H14
R&D % of sales	5%	13%	15%
# of US Filings	0	7	10

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



	Filed	Under development	Total
Number of ANDAs	13	12+	25+

(1) IMS Health MAT Mar 2014
(2) IMS Health MAT Dec 2013

Contract services, manufacturing and license partners

- Vertically integrated model offering analytical services, formulation and commercial manufacturing
- Services over 100 customers in the pharmaceutical and biotechnology sectors, with approximately 75% being repeat customers
- Driven by a dedicated sales team, generating more than 700 quotes per year
- Specialises in the development and manufacturing of unique drug products that require non-traditional handling and testing, a niche that requires a high level of scientific expertise
- Formulation development and manufacturing is focused on oral solid dosage forms (tablets and capsules) but also includes oral liquids and topical powders
- Expertise in first time in human (FTIH), phase I, II, III clinical trial manufacturing having conducted 75 FTIH projects over the last 5 years for new chemical entities

Large and diversified customer base

Future catalysts for value

Growth strategy

US retail generics maximisation

- Approval and launch of filed FDA products
- Optimise market penetration of product portfolio
- Portfolio expansion through growing product pipeline
- Paragraph IV

Doxycycline franchise optimisation

- Build doxycycline generic portfolio
- Optimise market penetration of product portfolio
- New patent granted to 2028

Itraconazole commercialisation

- Launch Lozanoc™ in Australia
- Commercialise Lozanoc™ in Europe, US, Korea, Japan and China

Strategic acquisitions, licensing and partnership arrangements

- Execution of licensing arrangements for niche generic and/or specialty products
- Product and enterprise acquisitions with strong growth potential and immediately accretive
- Build an injectable and pain portfolio in Australia
- Clinical development of itraconazole in cancer through HPPI