ASX Announcement

22 February 2019

MAYNE PHARMA REPORTS STRONGER 1HFY19 RESULTS

- Revenues of $274.4m, an increase of 13% on 1HFY18
- Reported EBITDA of $65.4m, an increase of 184% on 1HFY18
- Underlying EBITDA of $81.2m, an increase of 16% on 1HFY18
- Underlying NPAT of $21.1m, an increase of 35% on 1HFY18
- Reported NPAT of $2.6m, following a loss in the prior corresponding period (pcp)
- Net operating cashflow of $53.5m up 11% on 1HFY18, despite a significant one-off impact from the extension of trading terms with a major wholesaler
- Specialty Brands benefited from stronger sales and gross profit performance of FABIOR®, SORILUX® and DORYX®
- Generic Products gross profit grew 58% on pcp driven by lower stock obsolescence and favourable product sales mix
- Received US Food and Drug Administration (FDA) approval for TOLSURA™ (SUBA®-itraconazole) antifungal capsule and established a new hospital-based field team to promote
- Strengthened dermatology portfolio with acquisition of LEXETTE™ (halobetasol) foam[1] and multi-source EFUDEX® (fluorouracil) cream
- Assumed control of SUBA-itraconazole Basal Cell Carcinal Nevus Syndrome (BCCNS) program from HedgePath Pharmaceuticals, Inc. (HedgePath)

Mayne Pharma's CEO, Mr Scott Richards said, "With a stronger balance sheet, improved cashflow, a diverse operating model that includes specialty branded and multi-source (generic) product platforms, and contract development and manufacturing services, we have reported revenue up 13%, underlying EBITDA up 16% and underlying NPAT up 35% on pcp. Reported EBITDA was up 184% and reported NPAT was $2.6m impacted by a number of one-off non-cash items and the increased expensing of research and development spend. Specialty Brands tripled sales and gross profit with FABIOR, SORILUX and DORYX all contributing to growth versus pcp, and Generic Products reported much stronger gross profit despite the entrance of a number of new competitors into the dofetilide market."

Summary of results[1]

			Change on pcp	
$m	1HFY19	1HFY18	$m	%
Reported revenue	274.4	243.3	31.1	13%
Reported gross profit	160.4	95.9	64.5	67%
GM%	*58%*	*39%*		
EBITDA – underlying[2]	81.2	69.9	11.3	16%
EBITDA – reported	65.4	23.0	42.4	184%
Net income / (loss) – underlying[2]	21.1	15.6	5.5	35%
Net income / (loss) - reported	2.6	(174.2)	176.8	nm
Cash flow from operations	53.5	48.0	5.5	11%

1. Earnings attributable to members of the Company with exception of cash flow which is consolidated.
2. Adjustments to EBITDA in 1HFY19 include $4.2m non-cash credit arising from an increase in the fair value of earn-out liabilities, $1.5m of legal costs associated with drug pricing investigations, $8.4m non-cash fair value restatement of HedgePath warrants and $1.7m to remove HedgePath losses. Net income also excludes US tax rate change and the tax effect of those items.

[1] LEXETTE tradename is conditionally acceptable to FDA

"The first half saw the completion of many strategic investments such as the acquisition of two dermatology products – LEXETTE (halobetasol) foam and multi-source fluorouracil cream to broaden our dermatology offering. We also invested in a new hospital-based field team to promote TOLSURA (SUBA-itraconazole) which was approved by the FDA during the period, and lastly we took control of the SUBA-itraconazole BCCNS program from HedgePath Pharmaceuticals, Inc. We remain focused on our key strategic initiatives which are centered on providing value to patients and prescribers in dermatology, womens health and infectious disease through the provision of an innovative offering of complementary proprietary and multi-source products in each therapeutic category."

Operating Performance

Specialty Brands Division (SBD)

The SBD operating segment's sales were $43.3m, up 213% on 1HFY18 and gross profit was $37.8m up 227% on pcp. In US dollar terms, SBD's sales were US$31.3m, up 190% on 1HFY18 and gross profit was US$27.4m, up 204% on pcp.

All products contributed to growth with FABIOR up 97%, SORILUX up 73% and the DORYX family up 780% versus pcp. The two foam products (FABIOR and SORILUX) have benefited from an expansion of the dermatology sales team and additional marketing investments. The strong growth in DORYX reflects elimination of the abnormal one-off DORYX returns which impacted the prior period and favourable product sales mix. Adjusting for DORYX returns in the prior period, SBD sales were up 53% in 1HFY19 on pcp.

In terms of underlying demand as measured by dispensed prescription data, FABIOR was up 52% and SORILUX was up 114% in 1HFY19 versus pcp[2]. Whilst the TRx performance of the DORYX family was down slightly, the DORYX family (brands and generics) holds more than 60% of US doxycycline delayed-release prescriptions[2].

Generic Products Division (GPD)

The GPD operating segment's sales were $175.9m, down 3% on 1HFY18 and gross profit was $100.3m, up 58% on pcp. In US dollar terms, sales were US$127.4m down 10% on 1HFY18 and gross profit was US$72.6m up 47% on pcp.

Key drivers of the improved gross profit were the launch of liothyronine in January 2018, the acquisition of fluorouracil and normalised stock obsolescence. Dofetilide was impacted significantly by the approval of a number of competitors with sales down 73% to US$9m driven by pricing pressure, market share loss and shelf stock adjustments. Excluding dofetilide, GPD sales and gross profit were up 10% and 112% respectively on pcp in US dollar terms.

Gross profit margin strengthened to 57%, up from 35% in the pcp, driven by favourable product sales mix and cost savings from the transfer of select products into Greenville and Salisbury from third party manufacturers. We expect to transfer more than 20 products in-house or into third party contract manufacturing organisations which is expected to significantly lower product costs over time.

[2] IQVIA weekly TRx, 8 Feb 2019

The Company remains focused on building a more resilient multi-source business through expanding its channels to market and participating in other parts of the value chain. A key focus of Mayne Pharma is to get closer to the patient, and find more efficient and cost effective ways to supply products to improve patient access.

Metrics Contract Services (Metrics or MCS)

The MCS operating segment's sales were $33.9m, up 14% on 1HFY18 and gross profit was $16.5m up 4% on pcp. In US dollar terms, sales were up 6% on pcp to US$24.5m.

Metrics is benefiting from the investments made in Greenville over the last three years to transform manufacturing capacity and capability. The new solid oral dose manufacturing facility which was opened in April 2018 is enabling Metrics to exploit a new recurring revenue stream related to commercial manufacturing services. During the half, Metrics added two further commercial manufacturing clients and is in the process of transferring these products into Greenville.

The pipeline of committed business grew 34% over the last twelve months reflecting the growing pipeline of potential commercial manufacturing opportunities. Metrics is expected to become an approved supplier in more than 6 marketing applications over the next twelve months. This captures on-market commercial products that Metrics is in the process of qualifying at the Greenville site and further products pending at regulatory agencies around the world.

Mayne Pharma International (MPI)

The MPI operating segment's sales were $21.3m up 13% on 1HFY18 and gross profit was $5.8m up 17% on pcp. The stronger sales and gross profit performance was driven by growth in key specialty products - MONUROL® (fosfomycin trometamol) and UROREC® (silodosin) and growing sales of SUBA-itraconazole and morphine sulfate globally.

Pipeline

Mayne Pharma continues to invest in the development of new brand and multi-source products focusing on hard to develop and manufacture products in three key therapeutic areas – dermatology, women's health and infectious disease. The Company will continue to strengthen the pipeline through internal R&D, strategic alliances and business development.

In 1HFY19 research and development spend was $23.1m of which more than 75% was directed towards programs in these three therapeutic areas. The additional brand spend in 1HFY19 has resulted in the level of R&D capitalisation declining to 49% from 80% in the pcp.

During the half, the Company received FDA approval for two products including the New Drug Application for TOLSURA (SUBA-itraconazole) anti-fungal capsule which launched in the US in January this year through a new hospital based field team calling on infectious disease / pulmonology physicians.

The Company has eight dermatology programs in development including a phase III program (SUBA-itraconazole in BCCNS) and a phase II program (trifarotene in Congenital Ichthyosis). During 1HFY19, the Company assumed control of the SUBA-itraconazole BCCNS program from HedgePath. The Company now fully controls all development and commercial aspects of this

program and plans to invest in a phase III pivotal clinical trial which is required to bring this product to patients in various markets around the world, including the US.

The Company has four women's health pipeline products including a multi-source NUVARING® pending with the FDA, which is the largest contraceptive sold in the US$5.4b[3] US contraceptive market with no generic equivalents today. The Company is working closely with its development and manufacturing partner, Mithra Pharmaceuticals, SA and expects to respond to the FDA's questions on this product later in 2019.

Mayne Pharma's development pipeline includes over 25 multi-source products targeting US markets with sales greater than US$5b[3]. The Company has 14 products pending approval at the FDA with a total market value of more than US$3b[3] of which eight products have no generic equivalents today.

Debt and Cash Flow

The Company achieved positive net operating cash flow after interest, tax and working capital of $53.5m up 11% on the prior period. This was adversely impacted by a $35m increase in working capital driven by an extension of trading terms this half from one of the major wholesalers which is not expected to repeat in the second half.

The Company had net debt of $298.8m, cash on hand of $96.2m and has significant room within its bank covenants, with leverage at 1.5x, and retains US$190m of undrawn debt.

Outlook

The US pharmaceutical market remains the world's largest pharma market representing 44%[4] of global sales and continues to be extremely dynamic with potential government policy changes and ongoing channel shifts through vertical integration of the supply chain across wholesalers, retailers, pharmaceutical benefit managers and insurers. The Company remains focused on participating in other parts of the value chain and finding more efficient and cost effective ways of getting products to patients.

Like many of our competitors, the performance of Generic Products will be more variable period to period depending on the timing of new product launches, cost savings from the transfer of products into Greenville, Salisbury or third party manufacturers, any competitor launches or withdrawals on key products and portfolio optimisation. The Company is currently facing emerging near-term competitive pressures on some key products as well as potential opportunities from market supply disruptions. Importantly, the Company continues to transition its business towards more resilient therapeutic areas that are channel focused to create a sustainable multi-source business over the longer term.

The Company expects to benefit from the recent brand launches of LEXETTE and TOLSURA, which are expected to be key drivers of strong growth for Specialty Brands, together with the growing pipeline of committed contract service revenues and new product launches from the pipeline of products pending at the FDA which includes several potential first-to-market opportunities.

[3] IQVIA MAT Sales Dec 2018
[4] IQVIA MAT Sales Jun 2018

The Company will continue to maintain a conservatively structured balance sheet and drive organic growth and pursue shareholder value accretive business development opportunities, while improving profitability and cashflow through an efficient operating model.

For further information contact:
Scott Richards +61 3 8614 7777
Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

About Mayne Pharma

At Mayne Pharma we believe that everyone deserves medicines that are better, safe and more affordable. That's why our people are determined to create innovative products and services for our changing world.

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation of complex oral and topical dose forms including potent compounds, modified-release products and inherently unstable compounds.

EFUDEX®, MONUROL®, UROREC® and NUVARING® are registered trademarks of third parties.