ASX Announcement

24 February 2021

MAYNE PHARMA REPORTS 1HFY21 RESULTS

- Reported revenues of $208.8m, down 8% on 1HFY20
- Reported EBITDA of $40.5m, up 17% on 1HFY20 and underlying EBITDA of $39.9m, down 16% on 1HFY20
- Constant currency underlying EBITDA was $44.0m down 7% on the prior corresponding period (pcp)
- Reported net loss after tax of $181.3m driven by intangible asset impairment associated with the generic business
- Specialty Products rebounded strongly from soft 2HFY20 and dermatology restructure drove improved profitability
- Potential FDA approval of NEXTSTELLIS™ in April 2021
- Metrics Contract Services grew sales 6% in USD terms on pcp
- Mayne Pharma International grew sales 10% on pcp
- Commenced marketing of four products in 1HFY21 – SOLTAMOX® oral solution, DORYX® 80mg delayed release tablets, generic KERYDIN® topical solution and chlorzoxazone tablets
- Significant opex reduction of $12m through streamlined global infrastructure and $7m reduction in product development spend
- Net operating cashflow of $46m
- Net debt reduced by $40m to $221m

Summary of results[1]

				Constant currency	
$m	1HFY21	1HFY20	Change %	1HFY21	Change %
Reported revenue	208.8	227.2	(8%)	219.4	(3%)
Reported gross profit	96.9	106.4	(9%)	101.9	(4%)
GM%	*46.4%*	*46.8%*		*46.4%*	
EBITDA – reported	40.5	34.6	17%	44.5	29%
EBITDA – underlying[2]	39.9	47.4	(16%)	44.0	(7%)
Net income – reported	(181.3)	(18.2)	nm	nm	
Cash flow from operations	46.2	53.2	(13%)	49.2	(8%)

Mayne Pharma's CEO, Mr Scott Richards said, "At a group level, results have been impacted this half by the weakening USD, challenging trading conditions from COVID-19 and a softer generic result. On a constant currency basis, reported revenue was down 3%, reported EBITDA up 29% and underlying EBITDA down 7%. We continued to deliver substantial cost savings across the business with operating and gross development spend down $19m versus the pcp and have delivered a solid cashflow result that enabled net debt to be reduced by $40m. At the bottom line, the net loss after tax was impacted by a non-cash intangible asset impairment of the generic portfolio."

[1] Earnings attributable to members of the Company with exception of cash flow which is consolidated. EBITDA excludes asset impairments.

[2] Adjustments to EBITDA in 1HFY21 include $5.6m credit arising from the decrease in fair value of earn-out liabilities, $1.9m of restructuring costs, $1.4m of legal costs associated with drug pricing litigation, $0.3m to remove Inhibitor Therapeutics, Inc. (INTI) losses attributable to members and $1.4m of NEXTSTELLIS related costs.

"We continue to adapt to the evolving COVID-19 pandemic, ensuring the health and safety of our employees and maintaining an uninterrupted supply of medicines and services. Pleasingly, our manufacturing output has continued to increase in our own facilities, and we have experienced minimal disruption to our third-party supply chain. Specialty Products which was most impacted by the COVID-19 pandemic due to the decline in physician prescribing rebounded in the 1HFY21 with USD revenue up 32% on the 2HFY20."

"In terms of the other operating segments, Mayne Pharma International reported solid revenue growth up 10% on pcp and Metrics Contract Services reported 6% revenue growth in USD terms. Generic Products USD revenue was down 8% on pcp reflecting ongoing challenges in the US generics market."

"Mayne Pharma's key near term priority is to successfully commercialise NEXTSTELLIS, a novel oral contraceptive containing a new estrogen – Estetrol, or E4, which has an FDA target action date in April 2021. If approved, NEXTSTELLIS will compete in the short-acting combined hormonal contraceptive market valued at US$4b according to IQVIA[3]. Our business plan is targeting peak net sales of US$200m which represents around 2% of the market by units. We have recently strengthened our Women's Health commercial team with a number of key leadership appointments with branded launch expertise and have made significant advancements in our go-to-market strategy as we prepare for a potential launch shortly after FDA approval. We continue to prudently control our spending on this product and have aligned any significant investment to confidence around approvability of the product. If approved, NEXTSTELLIS launch costs covering sales force, medical education and marketing activities are expected to be approximately US$10m in the 2HFY21."

"The Company continues to invest in activities that are focused on pivoting the business away from the retail generic segment into more sustainable areas in dermatology, women's health, infectious diseases and contract services. The Company has a number of other women's health pipeline products including a generic version of NUVARING® which we plan to resubmit to the FDA this quarter. We also continue to invest R&D dollars into our key specialty pipeline programs such as trifarotene which is in phase II clinical development and the development of SUBA®-itraconazole into broader therapeutic areas. We have made significant investments to increase the capacity and capability of our global contract service platforms as we continue to see strong growth momentum in this business driven by favourable market dynamics and a deep pipeline of committed business."

Operating Performance[4]

Specialty Products Division (SPD)

In US dollar terms, SPD's sales were US$29.1m, down 6% on 1HFY20 but were up 32% on the 2HFY20 benefiting from some recovery from COVID-19 conditions, and improved gross-to-net performance. Key products continue to be impacted by reduced managed care coverage which has been offset by proactive co-pay card changes. A key feature of the result was the significant

[3] IQVIA, MAT Sales, December 2020
[4] Segment operating performance has been assessed in local currency terms so comparison can be made on a like-for-like basis without impacts from movements in the US dollar.

decrease in operating expenses which have fallen by US$5m on pcp due to the restructure of the dermatology sales team, driving improved profitability.

The dermatology sales team works with an extensive network of specialty pharmacies to provide access to more than a dozen branded and generic products. SPD's mix of business continues to evolve with 87% of sales now through specialty pharmacy channels up from 78% in the pcp.

Metrics Contract Services (Metrics or MCS)

In US dollar terms, the MCS operating segment's sales were up 6% on pcp to US$27.8m and gross profit was up 12% on pcp, benefiting from new commercial manufacturing revenues and an improving business mix.

Metrics supports more than 55 projects across the pharmaceutical value chain with 52 products in development and five commercial clients. Commercial manufacturing performed strongly and now represents 14% of MCS revenue up from just 3% in the pcp. Metrics customers include 11 of the top 20 global pharma companies and MCS is now approved as a manufacturer in 40 countries.

Further investments have been made in the contract service business globally including facility enhancements (at both Greenville and Salisbury sites), new marketing investments and operational excellence programs to drive growth.

Generic Products Division (GPD)

In US dollar terms, the GPD operating segment's sales were US$78.7m, down 8% on pcp and gross profit was US$27.5m, down 12% on pcp.

GPD performance was impacted by ongoing pricing pressures across the portfolio. There was mixed performance across key products with growth in budesonide and carbidopa/levodopa, offset by weaker performance of butalbital, methylphenidate and amiodarone. The two largest generic products were carbidopa/levodopa and liothyronine which both account for 13% of GPD revenue. In the 2HFY21 a new generic competitor has launched on liothyronine.

GPD saw limited benefit from new product launches in the 1HFY21, however three new generic oral contraceptive products have been launched since the start of the 2HFY21. The Company continues to optimise its supply chain to drive improved product costs with 12 product transfers expected to be completed in FY21.

Mayne Pharma International (MPI)

The MPI operating segment's sales were $21.3m up 10% on FY19 and gross profit was $6.9m up 38% on pcp. Contract services and contract manufacturing revenue which represent 44% of MPI revenue increased 35% on pcp and benefited from additional contract development projects and growth in contract manufacturing revenues. Seven new contract service projects were added in the 1HFY21 up from two in the pcp. The improving gross margin also reflects overhead recovery benefits in the Salisbury facility with overall output dose volumes up almost 50%.

NEXTSTELLIS (E4/DRSP) oral contraceptive

NEXTSTELLIS, the novel combined oral contraceptive licensed from Mithra Pharmaceuticals SA is under active review at the FDA and TGA with potential approval in both markets across 2021. NEXTSTELLIS contains a new estrogen called Estetrol, or E4, in combination with a progestin, drospirenone. If approved, E4 will be the first new estrogen introduced in the US for contraceptive use in 50 years. E4 is a low-impact estrogen with a unique mechanism of action that offers potential advantages over other estrogens used in contraception. This product has been studied in more than 4,000 women in phase II and phase III trials. The phase III trials met efficacy endpoints and demonstrated good bleeding control and a phase II trial showed a favourable effect on certain markers associated with blood clotting.

NEXTSTELLIS will compete in the short-acting contraceptive market in which more than 10 million American women and 1 million Australian women use combination (estrogen + progestin) oral pills, patches or vaginal rings. The target combined hormonal contraceptive markets are valued at US$4b in the US and A$70m in Australia according to IQVIA.

Debt and Cash Flow

The Company achieved positive net operating cash flow of $46.2m and free cash flow of $27.5m up 91% on pcp. Significant cash flow items during the period include $11.5m in gross R&D spend, $9.7m in payments for intangible assets and earnout payments, $13.9m in tax receipts, $6.4m in capital expenditure and $9.6m increase in working capital. Excluding the movement in working capital and tax refunds, net operating cashflow was consistent with the pcp.

The Company extended its syndicated bullet facility during the period to November 2024 and further deleveraged the balance sheet. Net debt was $220.6m at 31 December 2020 decreasing by $39.6m from 30 June 2020 benefiting from FX movements and good free cashflow generation. The Company improved its covenant terms in the period and retains significant buffer within its bank covenants, with leverage of 2.0x down from 2.5x at 30 June 2020 and shareholders' funds of $779m, above the covenant of $600m.

Outlook

Mayne Pharma's performance will be heavily influenced by the effective execution of its strategic priorities and will depend on many factors including movements in the US dollar, the timing of FDA approvals and competitor launches and withdrawals on key products. The US retail generic market continues to be highly competitive with increased pressure driven by new entrants in certain on-market and pipeline products.

The key strategic priority is to return Mayne Pharma to growth through repositioning the Company into sustainable products, distribution channels and therapeutic areas. Key drivers of this transformation are expected to be the successful commercialisation of NEXTSTELLIS and other key pipeline products pending at the FDA, accelerating the growth of the global contract service platform, continue to expand the portfolio of dermatology and women's health products through business development activities and R&D and maximise the SUBA-itraconazole franchise with TOLSURA®.

Further information

Additional details about Mayne Pharma's results are included in the Company's financial statements, investor presentation slides and webcast, all of which can be found on Mayne Pharma's website www.maynepharma.com. For further information please contact:

Scott Richards +61 3 8614 7777
Lisa Pendlebury +61 419 548 434, lisa.pendlebury@maynepharma.com

About Mayne Pharma

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

Mayne Pharma has a 40-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 continue to be marketed around the world.

Mayne Pharma has two facilities based in Salisbury, Australia and Greenville, USA with expertise in the formulation of complex oral and topical dose forms including potent compounds, modified-release products and poorly soluble compounds.