ASX Announcement

25 February 2022

MAYNE PHARMA REPORTS 1HFY22 RESULTS

- Reported revenues of $196.4m, down 6% on 1HFY21
- Reported EBITDA of $48.8m, up 20% on 1HFY21 affected by the non-cash NEXTSTELLIS® deferred consideration reassessment due to COVID and associated longer time period for physician and patient activation and higher cost of payer coverage and reimbursement
- Reported net loss after tax of $50.4m driven by intangible asset impairment associated with the generic business
- Underlying EBITDA of $23.7m, down 38% on 1HFY21
- Underlying EBITDA of $44.4m excluding NEXTSTELLIS launch investment, up 11% on 1HFY21 and up 35% on 2HFY21
- Expense reduction excluding NEXTSTELLIS launch investment of $8.0m or 12% versus 1HFY21
- Solid growth across key performance metrics for NEXTSTELLIS in 2QFY22 versus 1QFY22
- Metrics Contract Services delivered 20% revenue growth on 1HFY21
- International delivered 29% revenue growth on 1HFY21
- Entered into five new supply agreements in the 1HFY22 with leading pharma companies to add 12 products to the dermatology portfolio
- Dermatology benefited from eight product launches in the 1HFY22 with generic ABSORICA® (isotretinoin) becoming the largest US product by revenue
- Recently launched three dermatology products in the 2HFY22 targeting addressable markets of US$450m[1] including a top three dermatology product by IQVIA sales, generic ACZONE® (dapsone) and generic PROTOPIC® (tacrolimus)
- Received Therapeutic Goods Administration (TGA) approval of NEXTSTELLIS and Swissmedic approval of KAPANOL® for Opioid Substitution Therapy (OST)
- Renegotiated debt facilities to increase flexibility

Summary of results[2]

$m	1HFY22	1HFY21	Change on pcp	2HFY21	Change on 2HFY21
Reported revenue	196.4	208.8	(6%)	192.0	2%
Reported gross profit	89.3	96.9	(8%)	85.1	5%
GM%	*45.5%*	*46.4%*		*44.3%*	
EBITDA – reported	48.8	40.5	20%	25.6	91%
EBITDA – underlying[3]	23.7	38.5	(38%)	25.0	(5%)
EBITDA – underlying (excl. NEXTSTELLIS)	44.4	39.9	11%	32.8	35%
Net loss - reported	(50.4)	(181.3)	nm	(27.1)	nm

[1] IQVIA, MAT Sales, December 2021

[2] Earnings attributable to members of the Company. EBITDA excludes asset impairments.

[3] Adjustments to EBITDA in 1HFY22 include $32.1m credit arising from the decrease in fair value of earn-out and deferred consideration liabilities, $3.7m credit for the sale of land, $5.6m of exit costs for discontinued products, $3.4m of restructuring costs, $1.6m of legal costs and $0.1m to remove Inhibitor Therapeutics, Inc. (INTI) losses attributable to members.

CEO commentary

Mayne Pharma's CEO, Mr Scott Richards said, "At a group level, our underlying results this half have incorporated our significant investment in commercial infrastructure to support the launch of NEXTSTELLIS. Pleasingly, excluding our NEXTSTELLIS investment, underlying EBITDA was up 11% on the 1HFY21 and up 35% on the 2HFY21 despite our retail generics business segment continuing to erode as a result of the sustained competitive pricing environment. Encouragingly, Metrics Contract Services, International and our dermatology portfolio delivered double digit earnings growth versus pcp. At the bottom line, we reported a net loss after tax which was impacted by a non-cash intangible asset impairment of the generic portfolio."

"We made significant progress with the launch of NEXTSTELLIS and 2,100 healthcare professionals (HCPs) have now written the product since launch, the bulk of which came in the 2QFY22. This is particularly pleasing given the COVID pandemic and the recent Omicron variant which have impacted the uptake of NEXTSTELLIS due to reduced access to physicians and material absences in the sales team. Despite these headwinds, we are approaching acquiring 100 new writers in a week and the aided awareness of NEXTSTELLIS amongst our target HCPs has grown to 79%. Payer commercial coverage is critical to ensuring affordable access to the brand and we currently have 55% of commercially insured patients with unrestricted access and ~70% with access including restrictions which is in line with expectations and the experience of other brands in this market at this stage of their launch cycle."

"Notwithstanding the challenging operating environment, we are excited about the potential of NEXTSTELLIS to become a leading brand in the US$3.4b contraceptive market based on the trajectory we are seeing with new writers, dispensed prescriptions and commercial insurance coverage. We expect continued positive momentum in 2022 across these key indicators, together with the influence of a targeted direct-to-consumer marketing campaign which we plan to roll-out later this calendar year."

"Mayne Pharma has a diverse business model with multiple opportunities for growth and potential near-term value creation. Whilst NEXTSTELLIS is the most significant commercial opportunity, the Company has a number of other high-quality assets. Metrics, our US Contract Service business participates in the highly attractive CDMO[4] market and has demonstrated a solid track record of double-digit revenue CAGR over the last eight years. Our dermatology business returned to strong earnings growth this half and is expected to significantly benefit from three recent launches targeting addressable markets of US$450m. Our International business has an advanced pipeline of near-term new product launches including the Australian launch of NEXTSTELLIS and the European launch of KAPANOL into the OST market."

Chair commentary

Mr Frank Condella, who assumed the Chair of Mayne Pharma four months ago, said, "Your Board is disappointed in the impact that our retail generics business continues to have on the overall financial performance of the group. Over the last four years, Mayne Pharma has repositioned its business away from retail generics into more sustainable segments such as women's health, dermatology and contract services. These segments now represent 80% of reported gross profit and pleasingly grew 20% at the revenue line versus pcp. In late 2019, we made the decision to license and invest in NEXTSTELLIS, a potential transformational opportunity in the women's health

[4] Contract development and manufacturing organisations

space. The launch of this product is gathering momentum despite the headwinds of COVID and we remain optimistic about its potential. We are also continuing to evolve our US products go-to-market approach by actively participating in the disintermediation of the US pharma value chain through new partnerships and our innovative dermatology model."

"The Mayne Pharma Board and the executive management team are committed to turning around performance and seeking to maximise shareholder value."

"We commenced a program of Board renewal in the first half of this fiscal year adding two new US based directors with deep pharmaceutical experience who are already helping to guide the Company strategically. Dr Carolyn Myers and Dr Kathryn MacFarlane both have more than 30 years of industry experience and established track records in creating, growing, and leading US healthcare businesses."

"The Board is proactively exploring all options to unlock the value of Mayne Pharma's businesses for the benefit of shareholders. These initiatives are expected to become evident over the 2022 calendar year."

Operating Performance

Metrics Contract Services (Metrics or MCS)

The Metrics business continues to outperform with revenues up 20% on pcp to $46.0m, gross profit up 33% and direct contribution up 37% to $22.1m. Metrics benefited from new commercial manufacturing revenues which now represent 27% of segment revenue up from 14% versus the pcp. Formulation development revenues were up 10% in USD terms benefiting from five new clients and 23 new projects in the 1HFY22 and reflect the deeper investments made in business development.

The CDMO market remains highly attractive with the small molecule segment continuing to grow in the mid-single digits, well above the broader pharmaceutical industry benefiting from an increase in outsourcing activity and the growing number of molecules in clinical development. M&A dynamics remain robust and Metrics is well regarded with its unique and differentiated platform in the high potency small molecule market. Metrics supports 12 of the top 20 global pharma companies and is one of a few US based potent solid oral dose CDMOs for early-stage development through to commercialisation from a single FDA registered site.

The pipeline of committed business continues to trend favourably with a strong pipeline of near-term commercial manufacturing opportunities expected to add further recurring revenue streams and provide positive trajectory into FY23.

International

The International operating segment's revenues were $27.6m up 29% on 1HFY21, gross profit was $8.8m up 27% on pcp and direct contribution was up 155% to $4.1m. All business lines delivered double digit growth with Australian product revenues up 15% to $10.0m, benefiting from the launch of SOLARAZE® (diclofenac) gel to treat actinic keratoses and a PBS price increase on erythromycin. CDMO revenue grew 39% to $17.6m and benefited from new formulation development contracts and growing sales of KAPANOL® (morphine) in Canada and Switzerland.

The early-stage contract development business now has 21 active projects, up from nine in the pcp and represents an important growth platform in the International business. The Australian business has a proven track record of commercialising products with over 70 product launches globally over the past decade

The International segment has a solid pipeline of near-term launches including NEXTSTELLIS oral contraceptive, which was approved by the TGA in November 2021 and KAPANOL (morphine) used to treat Opioid Substitution Therapy (OST) which was recently approved for OST in Switzerland. Both products are expected to launch across CY22.

Branded Products Division (BPD)

BPD's revenues were $4.2m, up 185% on 1HFY21, gross profit was $3.3m up 142% and direct contribution was a loss of $22.5m due to the investment in the NEXTSTELLIS US commercial launch.

In USD terms, NEXTSTELLIS revenues were US$1.1m and operating expenses were US$15.7m. TOLSURA® (itraconazole) capsule sales were US$1.3m up 61% on pcp and SOLTAMOX® (tamoxifen) oral solution sales were US$0.7m up 188%.

Portfolio Products Division (PPD)

PPD operating segment's revenues were $118.6m, down 20% on pcp, gross profit was $52.6m, down 25% on pcp and direct contribution was $36.7m down 29% on pcp. Performance versus the 2HFY21 was stronger at the earnings line with direct contribution up 4% reflecting the significant rebound in the dermatology portfolio.

PPD performance was impacted by ongoing pricing pressure and additional competition across the retail generic portfolio. The Company continues to rationalise the generic portfolio and discontinue unprofitable generic products, reduce stock obsolescence and optimise its cost base through realignment of its supply chain with raw material suppliers and CMOs.

Dermatology revenues were $41.7m up 8% on pcp and direct contribution was up 32% on pcp to $21.6m. Dermatology benefited from the launch of eight products with isotretinoin becoming the largest US product by sales in the 1HFY22.

In CY21, the Company has entered into a number of new dermatology partnerships with leading pharmaceutical companies including Sandoz, Upsher Smith, Torrent and Cosette. The recent partnering success validates the Company's unique go-to-market approach in dermatology which focuses on providing better outcomes for patients, prescribers, and pharmacy partners.

Debt and Cash Flow

The Company ended the half with net debt of $272.6m. Cash on hand was $114.7m at 31 December 2021 and the Company had borrowing of $387.3m. The Company remains compliant within all bank covenants with the leverage ratio 3.2x (covenant <4.25x), interest cover 7.7x (covenant >3x) and shareholders' funds of $754m (covenant >$600m) at the end of the period.

The Company achieved positive net operating cash flow. Excluding the movement in working capital and tax, net operating cashflow was $18.8m versus $41.9m in the pcp. Significant cash flow items during the period include $7.3m in gross R&D spend, earnout payments of $12.2m, $4.8m in capital expenditure and $18.3m increase in working capital to support the launch of NEXTSTELLIS and the new dermatology products.

Outlook

Mayne Pharma's success and performance will be heavily influenced by the effective execution of its strategic priorities and will depend on several factors including the timing of FDA approvals, payer coverage and reimbursement, competitive intensity in key product areas and the ongoing impacts of COVID.

Key growth drivers in the near to mid-term are expected to be growth in the dermatology portfolio from recent product launches, the launch of a number of new products in international markets, the potential launch of a generic version of NUVARING® and further growth of Metrics Contract Services.

NEXTSTELLIS remains the Company's most significant commercial opportunity participating in the US$3.4b short-acting combined hormonal contraceptive market with nearly 10 million American women using CHCs for their contraceptive needs. Continued growth and productivity of new writers, greater payer coverage and the launch of the direct-to-consumer campaign are key factors that are expected to accelerate the sales trajectory of this product.

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:

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising 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.

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