ASX Announcement

27 August 2021

MAYNE PHARMA REPORTS FY21 RESULTS

- Reported revenues of $400.8m, down 12% on FY20 or down 3% on a constant currency basis
- Reported EBITDA of $66.1m, down 18% on FY20 or down 5% on a constant currency basis
- Reported net loss after tax of $208.4m driven by the intangible asset impairments which were incurred in the 1HFY21
- On a constant currency basis, underlying EBITDA of $86.5m (excluding NEXTSTELLIS® set-up costs), down 10% on FY20
- Significant opex reduction of $18.0m on a constant currency basis (excluding NEXTSTELLIS set-up costs) to optimise global infrastructure
- FDA approval and US launch of NEXTSTELLIS with all key lead performance indicators on track with plan
- Metrics Contract Services delivered double digit growth in USD terms with the 2HFY21 up 20% on the 1HFY21
- Restructure of dermatology platform drove significant improvement in profitability of Specialty Products
- Entered into four new supply agreements with leading pharma companies to launch up to 11 dermatology products across FY22 targeting addressable markets of US$500m[1]

Summary of results[2]

				Constant currency	
$m	FY21	FY20	Change %	FY21	Change %
Reported revenue	400.8	457.0	(12%)	441.2	(3%)
Reported gross profit	182.0	211.5	(14%)	200.4	(5%)
GM%	*45%*	*46%*		*45%*	
EBITDA – reported	66.1	80.6	(18%)	76.3	(5%)
EBITDA – underlying[3]	63.5	95.6	(34%)	73.2	(23%)
EBITDA – underlying (excl. NEXTSTELLIS set up)	75.4	95.6	(21%)	86.5	(10%)
Net income – reported	(208.4)	(92.8)	nm	nm	

Mayne Pharma's CEO, Mr Scott Richards said, "At a group level, results have been impacted by the weakening USD which had a $10m adverse impact on EBITDA, the COVID-19 pandemic and on-going challenges in the US retail generic sector. On a constant currency basis, reported revenue was down 3%, reported EBITDA down 5% and underlying EBITDA down 10% excluding NEXTSTELLIS set up costs. Pleasingly, all segments other than the Generic Products segment contributed to EBITDA growth compared to the prior corresponding period (pcp). At the bottom

[1] IQVIA MAT Sales, June 2021
[2] Earnings attributable to members of the Company. EBITDA excludes asset impairments.
[3] Adjustments to EBITDA in FY21 include $20.6m credit arising from the decrease in fair value of earn-out liabilities, $15.5m of restructuring costs, $2.1m of legal costs associated with drug pricing litigation and $0.4m to remove Inhibitor Therapeutics, Inc. (INTI) losses attributable to members.

line, the net loss after tax was impacted by the non-cash intangible asset impairments of the generic portfolio that occurred in the first half."

"Mayne Pharma continues to adapt to the evolving COVID-19 pandemic, ensuring the health and safety of its employees and maintaining an uninterrupted supply of medicines and services. We have continued to streamline our operations and reduce spend through supply chain optimisation, restructure of the dermatology sales team and the discontinuation of non-viable generic products. Excluding NEXTSTELLIS set up costs, operating expenses were reduced by $18.0m on a constant currency basis."

"In late June, we were delighted to launch NEXTSTELLIS, a new birth control option for women containing a novel estrogen – estetrol or E4. The launch is being supported by a highly experienced national sales team who are now in the field promoting NEXTSTELLIS to healthcare providers. The sales team has already had more than 20,000 in-person interactions with prescribers and reached more than 60% of priority prescriber targets within 6 weeks of launch. Further, more than 37,000 NEXTSTELLIS samples have been distributed to physician offices (one sample equals a 28-day cycle) with dispensed prescriptions expected to accelerate as women complete their trial period. We estimate approximately 5,000 women are currently trialling NEXTSTELLIS[4]. Strong progress has been made with managed care with commercial insurance coverage ahead of our internal goals. The key priorities with this launch are to educate the market about E4, gain broad payor acceptance and reimbursement, and ultimately become the preferred branded oral contraceptive in the market."

"The Company has significantly strengthened its US dermatology pipeline in recent months signing four supply and distribution agreements with leading suppliers for eleven dermatology products which treat key skin conditions such as acne, psoriasis and rosacea. Our partnering success validates our unique go-to-market approach in dermatology which focuses on providing better outcomes for patients, prescribers, and specialty pharmacies. All products have final FDA approval other than two which have tentative FDA approval. The two largest products with combined IQVIA sales of more than US$300m[5] are expected to be meaningful contributors to our business this fiscal year given current market conditions and competitive dynamics. The Company continues to prosecute its other programs pending at the FDA including a generic version of NUVARING®, which is targeting an addressable market of US$680m[5]."

Operating Performance[6]

Metrics Contract Services (Metrics or MCS)

The Metrics business has shown a high degree of resilience during COVID-19 with revenues up 10% on pcp to US$61.3m and gross profit up 18%. Metrics benefited from new commercial manufacturing revenues which now represents 20% of segment revenue up from just 8% in the pcp. In the 2HFY21, MCS revenue was up 20% on the 1HFY21 as the business continues to benefit from the investments made in broadening capacity and capability at the Greenville site.

Over the last eight years, Metrics has demonstrated a solid track record of growth, delivering a 12%

[4] Based on distribution of product samples to physician offices and estimated utilisation of samples by prescribers provided by company sales representatives. Estimate assumes a patient will use two samples on average
[5] IQVIA MAT Sales, June 2021
[6] 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

CAGR (compound average growth rate) in revenue. Its pipeline of committed business continues to trend favourably, and five development clients are expected to file New Drug Applications (NDAs) during FY22 leading to potential new recurring revenue streams from commercial manufacturing.

Metrics remains one of a few US based potent solid oral dose CDMOs for early-stage development through to commercialisation from a single contiguous site. The business supports 66 projects across the pharmaceutical value chain with 60 products in development and six commercial products. Its customers include 13 of the top 20 global pharma companies.

The CDMO market remains highly attractive and continues 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 strong with many businesses in the small molecule market being sold in this space for trailing 12-month EBITDA multiples in the mid to high teens.

Mayne Pharma International (MPI or International)

The MPI operating segment's sales were $42.8m up 1% on FY21 and gross profit was $13.2m up 20% on pcp benefiting from improved overhead recovery rates with growing production volumes. Contract services and manufacturing revenue grew 11% to $18.4m and Australian product sales grew 6% to $17.5m. International sales were weaker due to timing of ASTRIX® (aspirin) shipments to Korea and the end of a 40-year licencing deal in Europe for ERYC® (erythromycin).

The Company has been building its early-stage contract development business with 12 active projects, up from six in the pcp. These contract projects include oral solid dose, novel topical development and emerging medical cannabis development.

SOLARAZE® (diclofenac sodium) gel and ACTIKERALL® (fluorouracil and salicylic acid) topical solution were added to the Australian portfolio during the period. Both products are indicated for the treatment of actinic keratosis and will be promoted by the existing sales team focusing on dermatologists and general practitioners that specialise in skin cancer. Mayne Pharma filed NEXTSTELLIS (E4/DRSP) and FABIOR® (tazarotene) foam with the TGA with approval anticipated by end of FY22.

Specialty Products Division (SPD)

SPD's sales were US$53.3m, up 1% on FY20 and gross profit was US$43.8m, flat on the prior year.

Dermatology, the largest therapeutic category representing 89% of SPD sales, was down US$3.5m impacted by COVID-19 and reduced managed care coverage. In response to these ongoing market dynamics, the dermatology field team was restructured with opex decreasing US$9.1m on pcp driving improved segment profitability.

Branded Women's Health sales including the recently launched NEXTSTELLIS and SOLTAMOX® (tamoxifen) oral solution were US$3.5m. Infectious disease (or TOLSURA®) sales whilst up 16% on pcp to US$2.2m were impacted significantly by COVID-19 and reduced access to physicians.

Generic Products Division (GPD)

In US dollar terms, GPD operating segment's sales were US$152.8m, down 10% on pcp and gross profit was US$51.0m, down 21% on pcp.

GPD performance was impacted by new competition on key products and ongoing pricing pressures across the portfolio. In the 2HFY21, liothyronine faced two new competitors with sales declining 60% versus the 1HFY21.

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.

Debt and Cash Flow

The Company achieved positive net operating cash flow of $58.9m and free cash flow of $9.6m. Significant cash flow items during the period include $23.7m in gross R&D spend, $27.3m in payments for intangible assets and earnout payments (including the payment of US$11m to license partner Mithra Pharmaceuticals, SA on FDA approval of NEXTSTELLIS), $10.9m in net tax receipts, $17.1m in capital expenditure and $13.6m increase in working capital. Excluding the movement in working capital and tax, net operating cashflow was $61.7m versus $65.2m in the pcp.

Net debt was $248.8m at 30 June 2021, decreasing by $11.4m from 30 June 2020. The Company remains compliant within all bank covenants with the leverage ratio 2.6x (covenant <3.75x), interest cover 7.9x (covenant >3x) and shareholders' funds of $776m (covenant >$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 the ongoing impact of the COVID-19 pandemic, movements in the US dollar, the timing of FDA approvals, and competitor launches and withdrawals on key products.

Key growth drivers are expected to be the successful commercialisation of NEXTSTELLIS in the US and Australia, the launch of more than a dozen dermatology and women's health products in the US targeting markets with IQVIA sales of US$1.5b, accelerating the growth of Metrics Contract Services and International, and continued optimisation of the cost base.

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.

NEXTSTELLIS®, NUVARING®, SOLARAZE®, ACTIKERALL® and SOLTAMOX® are trademarks of third parties.