ASX Announcement

21 August 2020

MAYNE PHARMA REPORTS FY20 RESULTS

- Reported revenues of $457.0m, down 13% on FY19; 2HFY20 flat on 1HFY20
- Reported EBITDA of $80.3m, down 28% on FY19; 2HFY20 up 32% on 1HFY20
- Underlying EBITDA of $95.3m, down 27% on FY19; 2HFY20 flat on 1HFY20
- Reported net loss after tax of $92.8m driven by intangible asset impairment associated largely with the generic business
- Significant opex reduction of $16m to optimise global infrastructure and $15m reduction in product development spend
- Net operating cashflow of $100m down 6% on FY19; 2HFY20 up 16% on 1HFY20
- Net debt reduced by $32m to $248m (excluding lease liabilities)
- Generic Products performance stabilised in 2HFY20 and Metrics Contract Services delivered solid revenue growth
- Specialty Brands impacted by COVID-19 and challenging managed care environment
- Received US Food and Drug Administration (FDA) filing acceptance for the novel oral contraceptive NEXTSTELLIS™ (E4/DRSP) in the US
- Generic NUVARING® complete response letter submitted to the FDA
- Launched four generic products and filed three generic products with the FDA including a potential first-to-market women's health product with an addressable market of US$160m[1]
- Entered into long-term supply agreement with Novast Laboratories for 13 oral contraceptive products, including five new products not previously marketed by the Company targeting addressable markets of US$500m[1]

Summary of results[2]

$m	FY20	FY19	Change on pcp	2HFY20	1HFY20	Change 2H/1H
Reported revenue	457.0	525.2	(13%)	229.8	227.2	1%
Reported gross profit	211.5	290.9	(27%)	105.1	106.4	(1%)
GM%	*46%*	*55%*		*46%*	*47%*	
EBITDA – underlying[3]	95.3	130.9	(27%)	47.9	47.4	1%
EBITDA – reported	80.3	111.6	(28%)	45.7	34.6	32%
Net income – reported	(92.8)	(279.1)	nm	(75.3)	(17.5)	nm
Cash flow from operations	99.8	106.6	(6%)	53.6	46.2	16%

Mayne Pharma's CEO, Mr Scott Richards said, "While the COVID-19 pandemic has presented unprecedented challenges to our business, we have focused on ensuring the health and safety of our employees and maintaining an uninterrupted supply of medicines and services to our customers and patients around the world. Despite the impact from COVID-19, the Company's 2HFY20 results were in line with the 1HFY20, and pleasingly net operating cashflow up 16%."

[1] IQVIA, MAT Sales, June 2020

[2] Earnings attributable to members of the Company with exception of cash flow which is consolidated

[3] Adjustments to EBITDA in FY20 include $8.6m business turnaround and restructuring charge, $18.7m credit arising from the decrease in fair value of earn-out liabilities, $14.6m of abnormal gross to net adjustments, $4.9m inventory adjustments, $3.2m of legal costs associated with drug pricing litigation and $2.2m to remove Inhibitor Therapeutics, Inc. (INTI) losses attributable to members and restatement of the value of Mayne Pharma's INTI warrants and $0.3m of E4/DRSP transaction costs.

"At the bottom line, the Company reported a net loss driven largely by a non-cash intangible asset impairment of the generic portfolio. Whilst disappointing, this impairment acknowledges the on-going challenging competitive market dynamics of the US generic marketplace."

" Pleasingly, Generic Products stabilised in the second half reporting stronger gross profit than the first half and Metrics Contract Services delivered another outstanding result with revenue up 15% on the prior corresponding period (pcp). Specialty Brands, however, was impacted by new competition in the acne and psoriasis space, the COVID-19 pandemic dampened prescribing, and managed care continued to tighten. In terms of expenses, the Company executed meaningful reductions in its cost base, with operating and gross development spend down $31m versus pcp."

"In FY20, we have focused on repositioning our business for growth by restructuring our cost base, rationalising our generic portfolio and investing in sustainable products, distribution channels and therapeutic areas. We completed the licensing of NEXTSTELLIS[4] in the US and Australia and received FDA filing acceptance for this novel contraceptive product. The Company continues to have many other near-term opportunities for growth including the potential launch of generic NUVARING and other key pipeline products pending at the FDA including a potential first-to-market women's health product. We continue to advance our key specialty pipeline programs such as trifarotene currently in phase II clinical development and the development of SUBA®-itraconazole into broader therapeutic areas. We expect to commence a phase III trial in basal cell carcinoma nevus syndrome (BCCNS or Gorlin Syndrome) patients during FY21."

Operating Performance

Generic Products Division (GPD)

The GPD operating segment's sales were $253.0m, down 21% on FY19 and gross profit was $95.7m, down 42% on pcp. In US dollar terms, sales were US$169.8m down 26% on FY19.

GPD performance was impacted in FY20 by competition on the key products including liothyronine, dofetilide and butalbital. In addition, there were abnormal gross-to-net charges of $14.6m and inventory adjustments of $4.9m on discontinued products that are not expected to recur in FY21. Adjusted gross margin for these abnormal items would have been 43%, instead of 38% as reported.

GPD performance improved in the second half of FY20 with gross profit up 10% compared to the first half benefiting from manufacturing transfers into Salisbury and Greenville and reduced stock obsolescence.

Specialty Brands Division (SBD)

The SBD operating segment's sales were $78.8m, down 14% on the prior corresponding period (pcp) and gross profit was $65.4m down 18% on pcp. In US dollar terms, SBD's sales were US$52.9m, down 19% on FY19.

COVID-19 significantly impacted sales with lower patient starts due to a reduction in patient visits to physicians. Prescriptions were down approximately 15% across the dermatology portfolio in April and May 2020 versus pcp and TOLSURA® prescriptions also fell during this period after

[4] NEXTSTELLIS brand name conditionally accepted by the FDA

growing consistently across the first nine months of FY20. SBD was also impacted by some unfavourable changes in managed care coverage and new competitor launches.

In response to these changing market dynamics, the Company has restructured the dermatology sales team, which is expected to deliver US$12m of annualised operating expense savings with US$5m achieved in FY20.

Metrics Contract Services (Metrics or MCS)

The MCS operating segment's sales were $82.8m, up 15% on FY19 and gross profit was $39.4m up 11% on pcp. In US dollar terms, sales were up 8% on pcp to US$55.6m benefiting from new development programs and manufacturing revenues.

Metrics now has five commercial manufacturing clients up from just one in FY18 including supply agreements with two top 10 global pharma companies to manufacture approved oncology medications for the US, Europe, Japan and other international markets. Third party manufacturing revenues grew 50% on FY19 and now represents 8% of MCS sales and are expected to continue to increase in FY21 as further clients receive regulatory approval of their products. Over time, MCS expects to transition more of its development clients into full service clients utilising services from formulation development and analytical services through to commercial manufacturing.

Mayne Pharma International (MPI)

The MPI operating segment's sales were $42.4m up 4% on FY19 and gross profit was $11.0m consistent with the pcp. Contract revenue increased 11% on FY19 and benefited from new development projects and growth in contract manufacturing revenues.

Pipeline

The Company continues to direct its R&D spend to its specialty clinical programs focusing on trifarotene and SUBA-itraconazole. A global phase II trial commenced during the year with trifarotene in patients with lamellar ichthyosis, a rare disease causing significant skin scaling. The Company also continues to explore new therapeutic uses for SUBA-itraconazole including other systemic fungal conditions such as coccidioidomycosis (or valley fever) and BCCNS. A global phase III trial is expected to commence in FY21 in BCCNS patients.

Mayne Pharma's generic pipeline includes a dozen products targeting addressable markets with IQVIA sales of more than US$3b[5]. Five products were recently added to the pipeline from Novast Laboratories including generic equivalents of the two highest prescribed oral contraceptive products in the US – ORTHO CYCLEN® and ORTHO TRI-CYCLEN®. The Company also has a number of complex products pending at the FDA including generic NUVARING and a potential first-to-market women's health product with an addressable market of US$160m[5], both with FDA target action dates in 1HFY21. Generic NUVARING participates in an addressable market of US$960m[5] with one independent generic now approved.

[5] IQVIA, MAT Sales, June 2020

NEXTSTELLIS (E4/DRSP) oral contraceptive

NEXTSTELLIS, the novel combined oral contraceptive licensed from Mithra Pharmaceuticals SA during the period, is now being reviewed at the FDA with potential launch and approval in the second quarter of calendar 2021. In Australia, the Company is expected to file NEXTSTELLIS with the Therapeutic Goods Administration (TGA) this half with potential launch in the second half of calendar year 2021.

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. This combined hormonal contraceptive market is valued at US$4b according to IQVIA in the US and A$70m in Australia.

Debt and Cash Flow

The Company achieved positive net operating cash flow after interest, tax and working capital of $99.8m, down 6% on the prior period and net cash increase of $48.4m. Significant cash flow items during the period include $35.9m in payments for intangible assets and earnout payments, $32.7m in gross R&D spend, $50.2m decrease in working capital and $12.8m in net interest payments.

The Company had net debt (excluding lease liabilities) of $247.9m which decreased $32.5m during FY20. The Company retains significant buffer within its bank covenants, with leverage at 2.5x and shareholders' funds of $1.0b.

Outlook

The key strategic priority is to return 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 key pipeline products pending at the FDA (eg. NEXTSTELLIS and generic NUVARING), realising committed cost savings from new supply agreements and efficiencies in the manufacturing network and expanding sales in alternate non-retail channels. Contract services is expected to benefit from the pipeline of committed development business and growing manufacturing revenues. Specialty Brands is expected to benefit from its restructured dermatology cost base, a return to more normalised prescription patterns and further growth of TOLSURA that was negatively impacted by COVID-19.

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

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.

NEXTSTELLIS™, NUVARING®, ORTHO CYCLEN® and ORTHO TRI-CYCLEN® are registered trademarks of third parties.