ASX Announcement

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MAYNE PHARMA REPORTS 1HFY23 RESULTS

- Mayne Pharma positioned for growth through its US specialty pharma business and International segments
- BPD revenue up 112% vs 2HFY22 and 220% vs 1HFY22, driven by NEXTSTELLIS® growth
- Dermatology revenue down 78% vs 2HFY22 and 73% vs 1HFY22
- International revenue up 3% vs 2HFY22 and flat vs 1HFY22
- US retail generics revenue down 36% vs 2HFY22 and 38% vs 1HFY22
- Underlying EBITDA loss of $53.1m, down vs 1HFY22
- Cash used for operations in 1HFY22 $23.0m (excluding one-time restructuring and transaction fees of $33.8m)

Results overview

- Reported revenues (excluding discontinued MCS segment) of $101.2m, down 33% vs 1HFY22, largely attributable to the impact of continued competition in the retail generics market and on certain products in the dermatology business requiring normalisation of inventory in the distribution channel following higher channel inventory levels at the end of 2HFY22.
- Reported EBITDA loss of $99.2m reflects lower revenue, including as a result of commercial impacts of higher opening inventory levels in the dermatology distribution channel, discontinued unprofitable retail generic products and foreign exchange losses on hedges placed against receipt of MCS proceeds.
- Reported net loss after tax of $129.2m, driven by deferred tax asset write downs and intangible asset impairments following divestment of MCS.
- Underlying EBITDA loss of $53.1m, down 184% vs 1HFY22.
- Underlying EBITDA loss of $25.9m excluding NEXTSTELLIS® investment, down 136% vs 1HFY22.

Financial performance

- Branded Products Division (BPD) revenue of $13.4m, up 112% vs 2HFY22 and 220% vs 1HFY22 reflects strong growth in NEXSTELLIS® sales. Direct contribution loss of $25.5m reflects the continued investment into the US launch of NEXSTELLIS®
- Portfolio Products Division (PPD) revenue of $60.1m, down 52% on 2HFY22 and 49% on 1HFY22 is attributable to continued competition in the retail generic market as well as normalisation of inventory levels in the distribution channel following higher channel inventory levels at the end of 2HFY22. Direct contribution loss of $32.6m reflects negative contribution in both retail generics and dermatology during the half.
- International revenue of $27.6m is up 3% on 2HFY22 and flat on 1HFY22. Direct contribution of $2.8m declined reflecting the negative impact on International sales from the manufacturing operations.

Note: All amounts are in Australian dollars, unless specified otherwise

Successful close of MCS sale and announcement and completion of TXMD transaction

- MCS sale transaction was closed on 4 October 22 with gross proceeds of approximately $722.5 million. Utilised a portion of the proceeds to repay the $342 million syndicated debt facility in full. Note that statutory and underlying results for 1HFY23 are presented excluding this discontinued operation.
- Acquisition and completion of an exclusive product licencing transaction with TherapeuticsMD, Inc (TXMD) to secure a portfolio of on-market women's health products including three patent protected products: ANNOVERA®, IMVEXXY® and BIJUVA® and a portfolio of pre-natal vitamins. Transaction value was $US140 million (~$A212m) with a $US13.1 million (~$A18.1m) payment for acquired net working capital and pre-paid royalties. This portfolio of products generated US$90.6m of revenue in the 12 months to 30 June 2022, when distributed by TXMD. This transaction is highly complementary to the Company's strategy of growing scale in the US women's healthcare market and it leverages the existing women's health sales infrastructure. The transaction was funded by a combination of cash reserves, existing debt facilities and a $US27.95 million convertible note issued to Rubric Capital Management LP.

Sale of US retail generics portfolio to Dr Reddy's for US$90 million

- Announced sale of US retail generics business to Dr Reddy's Laboratories SA, a subsidiary of Dr. Reddy's Laboratories, Ltd (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) for upfront cash consideration of US$90 million (~$A133m), up to US$15 million in contingent milestone payments and an amount for working capital.
- Following the transaction, Mayne Pharma's commercial activities will be solely focussed on its US women's health portfolio, US dermatology and its International business.
- The Company will incur up to US$2 million in transaction costs and an estimated US$10 million in one-time restructuring costs. At close, the companies will enter into a 10 year supply agreement on arms-length terms for certain products manufactured at Mayne Pharma's Salisbury, South Australia facility.
- Completion is subject to customary closing conditions including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act), as amended, and is expected to close by the end of fiscal year 2023.

Cancellation of capital return

- The Board advised that it has decided to cancel the proposed pro-rata capital return as it is no longer considered by the Board to be in the best interests of the Company or its shareholders.
- Following the AGM, Mayne Pharma's strategic transformation has continued in line with its decision to build on its US Women's Health Portfolio through the TXMD transaction, which drew on a significant proportion of the Company's available cash.
- The second half of fiscal year 2023 has begun well and there is a clear path for a return to profitability. The Board believes it prudent to retain an appropriate balance sheet to support the business while it continues to assess the Company's capital structure.

Mayne Pharma's CEO, Mr Shawn Patrick O'Brien said, "The performance of our business during the first half of FY23 is categorised by building momentum in our Branded Products Division, very disappointing results in our Portfolio Products Division and a flat result in our International Division.

We have taken decisive action this half to address the issues that have created the disappointing results in both our PPD and International businesses. The second half of the year has begun well with new products in the market, and greater discipline in our commercial, sales and operational execution.

We have also made significant progress this half in our strategic transformation into a specialty pharmaceutical company with leading positions in women's health and dermatology. Following the completion of the MCS sale, we announced and completed the acquisition of a portfolio of highly complementary branded women's health products. Today's announcement of the sale of our US retail generics business to Dr Reddy's is another significant milestone for the new management team.

This sale accelerates the transformation and allows the Company to more exclusively focus on core areas of value for business growth in our targeted branded markets. We are creating a leaner Company with strong commercial and sales execution capabilities and with this transaction we move a step closer to achieving our goal of generating operating cash and returning the business to profitability.

The Board is supportive of our strategy and ambition, and the cancellation of the capital return is a prudent step to retain balance sheet flexibility whilst we drive improved operating performance, and the Board considers the appropriate capital structure to support profitable growth and a restoration of shareholder value."

Operating Performance

Branded Products Division

Continued momentum in NEXTSTELLIS® has driven strong revenue growth of 112% to $13.4 million vs 2HFY22 of $6.3 million. Gross profit grew to $10.7 million, up 162% on 2HFY22 whilst continued investment in the launch of NEXTSTELLIS® led to a 24% increase in direct operating expenses. Refreshed sales leadership and marketing strategies have delivered month on month prescription growth with a 50% increase over the period. NEXTSTELLIS® now accounts for ~80% of divisional sales.

Portfolio Products Division

A poor result across both retail generics and dermatology contributed to a revenue decline of 53% to $59.1 million and a direct contribution loss of $33.2 million, a decline from the $9 million profit in 2HFY22.

Dermatology performance was negative on 2HFY22 with sales of $11.2 million and negative contribution of $16.2 million, both down materially on a sequential basis following higher inventories at the end of June 2022, including as a result of new product launches during FY22. Results were also impacted by a competitive market placing negative pressure on pricing, and GTN adjustments. In addition, one-off adjustments on discontinued products contributed to the loss. The higher channel inventory was wound down through the half and largely normalised by period end.

As previously announced to the market, the net negative sales reported at the AGM for the 4 months to 31 October 2022 lead to a review of the methodology for estimating Co-Pay liability

accruals. The review and the implementation of a new methodology led to a restatement of FY22 net revenue and consequent adjustments to 1HFY23 net sales. The adjustment is related to the timing of revenue recognition and does not have an impact on cash in FY22 or FY23.

The performance of retail generics remains difficult with competition and volatility remaining elevated. Revenue of $59.1 million is down 35% on 2HFY22, and a direct contribution loss of $13.9 million was recorded vs a $3.3 million positive contribution in 2HFY22.

International

Revenue of $27.6 million was up modestly on 2HFY22 which was a disappointing result given strong demand for Australian and International product with sales negatively impacted by lower product availability. CDMO revenue was positive, however the direct contribution of the division declined by 28% to $2.8 million.

NEXTSTELLIS® has launched in Australia and is tracking to plan, with sales productivity improved and marketing activities gaining traction. Several opportunities for growth in international markets are progressing, particularly KAPANOL® for opioid substitution therapy (OST) in Switzerland. Further, the Company has committed to a capital expenditure program to modernise Salisbury with the assistance of a Federal Government Modern Manufacturing Initiative (MMI) Grant.

Balance Sheet and Cash Flow

The Company finished the half with a cash balance of $175.5 million following: (i) the receipt of cash proceeds for the sale of MCS, (ii) the repayment of the $342 million syndicated debt facility and (iii) the allocation of circa $222 million to complete the acquisition of the TXMD portfolio. Net cash position was $94.3 million with US$32 million drawn on the receivables finance facility and US$27.95 million of the convertible bond issued to Rubric Capital Management LP recognised as borrowings on balance sheet.

Cash flow from operating activities was negative $56.8 million for the half (including $33.8m in one-time restructuring and transaction fees) reflecting the difficult trading conditions with losses in both retail generics and dermatology and the continuing investment in NEXSTELLIS®.

In January 2023, the Company paid a special dividend of 2.72 cents per share ($46.7m).

Outlook

After a difficult half, Mayne Pharma has had an encouraging start to 2HFY23 as dermatology performance improves and the impact of greater scale in US women's health is delivered.

The addition of the complimentary women's health products ANNOVERA®, IMVEXXY® and BIJUVA® with NEXTSTELLIS® provides our women's health sales team an exciting portfolio to go to market. Momentum continues to build in NEXTSTELLIS® with week-on-week records in February and a sales plan to target improved financial performance with the goal to exit FY23 with a positive run rate contribution.

The TXMD portfolio is performing to plan with momentum building and the portfolio expected to deliver positive earnings and cash in 2HFY23.

Following a difficult half, a normalised sales cadence has returned, as demand for our products remains strong. New disciplines and processes following the Co-Pay accrual review provide more accurate and timely channel inventory and financial performance data.

The positive start to 2HFY23 underpins the anticipated return to positive contribution and cash generation. New launches of DORYX MPC® 60 mg and the recently announced licence with Galderma for an unbranded authorised generic version of ORACEA® for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients will add to growth.

Retail generics performance, for the period to deal closure, will benefit from the launch of diltiazem and HALOETTE® contraceptive, a generic version of NUVARING®.

The management refresh and investment in Salisbury is expected to drive an improved manufacturing performance to support strong product and contract demand.

NEXTSTELLIS® is anticipated to deliver solid results and there are several international market opportunities for KAPANOL® for opioid substitution therapy.

CEO, Mr Shawn Patrick O'Brien concluded

"We approach the second half with conviction and alignment to drive profitable growth across our business. Having added quality, high demand products to our portfolios with a refreshed approach to commercial excellence we are well positioned to rebuild earnings and cash and provide the best outcomes for our patients and partners while driving returns for our shareholders."

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.

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Authorised for release to the ASX by the Chair.

About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on commercialising novel and generic pharmaceuticals, offering patients better, safe and more accessible medicines. Mayne Pharma also provides contract development and manufacturing services to clients worldwide. Mayne Pharma has a 40-year track record of innovation and success in developing new oral drug delivery systems. These technologies have been successfully commercialised in numerous products that continue to be marketed around the world. To learn more about Mayne Pharma, please visit maynepharma.com.