mayne pharma

ASX Announcement

26 August 2016

MAYNE PHARMA DELIVERS EXCEPTIONAL FY16 RESULT

- Revenues of $267.3m, an increase of 89% on FY15
- Underlying EBITDA of $88.5m, up 143% on FY15
- Reported EBITDA of $76.9m, up 146% on FY15
- Reported net profit after tax was $37.4m, up 379% on FY15
- Achieved Doryx® EBITDA guidance of an average of US$2.7m/month over FY16
- Successful launch of dofetilide capsules, first generic to Pfizer's Tikosyn®
- FDA approval of next generation Doryx MPC tablets
- Significant growth expected in FY17 driven by the recent US generic product acquisition, new product launches and continued growth of Metrics Contract Services

Mayne Pharma's CEO, Mr Scott Richards said, "FY16 has been a strong year for Mayne Pharma with the business reporting growth at both the top line and bottom line as well as across all operating segments. The Doryx franchise, which was acquired in February 2015, achieved the earnings guidance set at that time and the launch of dofetilide, the Company's first generic product to be awarded 180-days of market exclusivity, made a meaningful contribution to the group result achieving a 100% return on investment in its first week following regulatory approval."

"The Company made significant investments in its facilities and product pipeline during the year with $29m spent on research and development and $30m spent on the multi-site expansion program announced 12 months ago. The strategic investments at Salisbury, South Australia and Greenville, North Carolina are well underway to support the pipeline of products under development and the 11 products that are expected to be brought in-house as part of the recently announced US generic product portfolio acquisition from Teva."

Summary of results[1]

			Change on pcp	
$m	FY16	FY15	$m	%
Revenue	267.3	141.4	125.9	89%
Gross profit	168.4	80.0	88.4	111%
GM%	*63.0%*	*56.6%*		
EBITDA – underlying[2]	88.5	36.4	52.1	143%
EBITDA – reported	76.9	31.3	45.6	146%
NPAT – underlying	45.2	13.4	31.8	237%
NPAT – reported	37.4	7.8	29.6	379%

1. NPAT and EBITDA is profit attributable to members of the Company.
2. Adjustments to EBITDA in FY16 include $5.2m non-cash credit arising from the decrease in the fair value of earn-out liabilities, $6.7m payment to settle a dispute with a former distributor, $6.8m of transaction and other related costs in relation to the recent product acquisitions, $1.3m of legal costs associated with US Department of Justice subpoena and $2.0m negative P&L impact of HedgePath Pharmaceuticals attributable to members of the Company. Reconciliation of underlying NPAT is detailed in accompanying FY16 Results Presentation which includes the tax effect of these adjustments.

Operating performance

Generic Products Division (GPD)

The GPD operating segment's sales were $106.8m, up 84% on FY15 and gross profit was $60.8m up 58% on FY15.

In US dollar terms, sales were up 60% to US$77.8m driven by the launch of the BAC tablet and dofetilide products and further market penetration by the oxycodone, hydrocodone and methamphetamine products, whilst nystatin was negatively impacted by more competitive market dynamics. Eight of the top ten generic molecules grew sales versus the prior period reflecting a combination of price and volume increases across the portfolio.

In June 2016, Mayne Pharma launched dofetilide capsules, the first generic approval to Pfizer's Tikosyn® in the US. Mayne Pharma was the first company to file a substantially complete ANDA containing a Paragraph IV certification for dofetilide capsules and as a result was awarded 180-days of market exclusivity. The dofetilide launch has been very successful, and in the latest week of prescription data available[1], Mayne Pharma's product accounted for 75% of the generic dofetilide market and 44% of the total dofetilide market.

Specialty Brands Division (SBD)

The SBD operating segment's sales were $77.8m and gross profit was $73.4m in FY16. In US dollar terms, SBD's revenue was US$56.7m. The division performed in line with the guidance that was outlined in February 2015 with the Doryx franchise achieving its monthly EBITDA target of US$2.7m on average across FY16. Since completion of the US$50m Doryx acquisition in February 2015, this franchise has contributed more than US$45m in EBITDA.

In the final quarter of FY16, Doryx faced new generic competition on the 50mg and 200mg dose strengths and the Company launched its authorised generic 50mg and 200mg products to participate in this newly formed generic market. In the latest week of prescription data available[1], the Mayne Pharma branded and generic products continue to account for more than 80% of the 50mg and 200mg market, with the authorised generics capturing more than 60% of the generic market.

Metrics Contract Services (MCS)

The MCS operating segment's sales were $48.9m up 45% on FY15 and gross profit was $26.4m up 55% on FY15. In US dollar terms, sales were up 26% to US$35.6m. The stronger gross profit margin reflects operating efficiencies, optimisation of pricing and an increased prevalence of later stage, higher margin development work. A new analytical laboratory efficiency program was implemented in the 2H16, which has delivered faster turnaround times for clients and added capacity through productivity improvements.

During the year, 18 new clients were added, the average value of quotes signed grew 44% on prior corresponding period (pcp) and the committed business pipeline[2] grew 30% over the year.

[1] IMS Health, US weekly dofetilide prescription volume, week ending 12 Aug 2016
[2] Committed business pipeline is the next 6 months of signed purchase orders / statements of work

The construction of the new Greenville manufacturing facility and investments in new equipment have contributed to the Company securing higher value, later stage project work.

Mayne Pharma International (MPI)

The MPI operating segment's sales were $33.7m up 6% and gross profit was $7.8m, up 7%. Australian sales grew 11% driven by the launch of a number of new products including noradrenaline injectable, which is the first generic competitor in this market, and oxycodone immediate-release tablets, which is a product originally developed in Greenville. Rest of World sales declined 10% driven by softer sales of Astrix® due to competitive market conditions in Korea in the first half, which reversed in the second half as previously foreshadowed.

Pipeline

Mayne Pharma's global development pipeline includes over 50 products, of which more than 40 products are targeting US markets with sales greater than US$7bn[3]. The Company has 19 products pending approval at the FDA with a total market value of more than US$1.8bn[3] and has four recently approved products launching in the 1HFY17 targeting markets with sales of US$600m.

In FY16 research and development spend was $28.6m with 79% capitalised over the period and more than 75% of this spend directed towards generic programs. During the year, the Company introduced eight new US pipeline products into development targeting markets with sales greater than US$1bn[3] and filed five products with the FDA. In Australia, the Company has more than 10 pipeline products of which four products are pending approval at the TGA.

In May 2016, Mayne Pharma received FDA approval for Doryx MPC tablets, a new formulation that incorporates a modified polymer coat that further retards the release of doxycycline in the acidic environment of the stomach. This product was launched in August and is expected to become a material part of the Doryx franchise over the coming year. Doryx MPC is patent-protected with one patent expiring in 2034 and two further patents have received Notice of Allowances from the US Patent and Trademark Office.

Commercialisation of Lozanoc® is continuing with the product recently launched in Germany. Lozanoc is now out-licensed in 15 countries and sold in Spain, Germany and Australia. Further countries are expected to launch in 2017 including Italy, the largest itraconazole market in Europe. Also during the period, the Company invested US$2.8m in HedgePath Pharmaceuticals Inc to support the ongoing clinical program using Mayne Pharma's patented oral formulation of Itraconazole to treat certain cancers. A Phase IIb study in Gorlin's Syndrome (a rare form of skin cancer) is currently underway with encouraging interim results. The FDA granted an Orphan Drug Designation to the product in June 2016.

Cash flow

The Company ended the year with net debt of $29.4m. Cash on hand at 30 June 2016 was $47.5m representing a decrease of $11.7m from 30 June 2015 and the Company had borrowings of $76.8m.

[3] IMS Health, MAT June 2016.

Notable cash flows during the period included $28.6m in payments for product development (both expensed and capitalised), $29.6m in capital expenditure, $10.7m in payments for US product acquisitions and $21.0m in earn-out and deferred settlement payments.

Net operating cash flow was $53.5m up 139% on the pcp after including $26.5m of tax payments, $6.7m one-off settlement payment with a former distributor and $8.1m for transaction and other one off costs.

Outlook

The outlook remains very positive and the Company has significant growth opportunities across multiple channels and all US business segments in the world's largest pharmaceutical market. Growth in FY17 will be driven by the recent product acquisitions, new product launches and further market penetration of the on-market portfolio globally.

The recently announced product acquisitions from Teva and GlaxoSmithKline will significantly enhance the GPD and SBD platforms and provide a stable base of revenue and earnings with growth to come from a combination of the launch of pipeline products, the re-launch of Fabior® and Sorilux®, and the delivery of revenue and cost synergies over time.

The Company will also continue to identify further business development opportunities to in-license or acquire complementary assets to expand the on-market portfolio and pipeline or introduce new manufacturing or technology platforms.

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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. 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 formulating complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.