



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Mayne Pharma Group

By **TIM BOREHAM**

ASX code: MYX

Share price: 21.5 cents; **Shares on issue:** 1,764,840,757; **Market cap:** \$379.4 million

Chief executive officer: Scott Richards

Board: Frank Condella (chair), Mr Richards, Prof Bruce Robinson, Patrick Blake, Ian Scholes. Dr Kathryn MacFarlane*, Dr Carolyn Myers

* Dr MacFarlane was appointed as of February 22, replacing Nancy Dolan. Dr Myers is Mithra Pharmaceuticals' board nominee.

Financials (half year to December 31 2021): revenue \$196.4 million (down 6%), underlying earnings before interest tax depreciation and amortization \$23.7 million (down 38%), net loss \$50.6 million (previously a \$181.3 million deficit), net debt \$272.7 million (down 9.5%)

Identifiable major holders: Estetra SRL (Mithra Pharmaceuticals) 9.6%, Investors Mutual 7.5%, Bruce Mathieson (and related entities) 6% (Lazard Asset Management ceased to be a substantial shareholder on February 17, having held 5.12%)

When it comes to analyzing company results, interpretations can differ as widely as Russian news agent Pravda's reporting of the Ukraine conflict relative to the Kyiv Independent's.

Take the reformed generic drug house Mayne Pharma, which last month gave the market its first glimpse of sales progress of its oral contraceptive Nextstellis since being launched in the US in mid-2021.

“We are still very early in the launch and we are still understanding KPIs (key performance indicators) but they are all beginning to move in a very positive direction,” purrs Mayne chief executive Scott Richards.

But in downgrading its recommendation on Mayne from a ‘buy’ to a ‘hold’, Bell Potter analyst John Hester says that early sales clearly have been “underwhelming”.

In its first (December) half-year accounts, the company (downwardly) revalued a \$32.1 million liability for earnouts and milestones it expected to pay to Mithra Pharmaceuticals, which in 2019 granted Mayne a 20-year exclusive licence for Nextstellis in the US.

In theory, a reduced liability in the accounts is a good thing - but not if it reflects a lowering of revenue expectations.

“It is worrying sign that Mayne is already recasting estimates on the timing of milestones and other payments only six months after the launch,” Mr Hester said in a research note.

Isn't diversity of opinion a wonderful thing?

More broadly, Mayne's half-year results were somewhat messy, but not entirely downbeat with all divisions bar retail generics recording double-digit revenue growth.

That's our interpretation, anyway.

Highlights were the contract drug manufacturing business and the company's dermatology range. The latter has become the biggest earnings contributor as Mayne moves from low-margin bog-standard generics to those with more zing: reworked drugs targeting specific or niche markets.

The Mayne story

While 85 percent of Mayne's revenue was derived from the US, the company sells more than 100 products in more than 15 countries. The company also manufactures drugs on a contract basis to more than 100 clients.

Mayne has an intricate history, but its DNA can be traced to the Adelaide based institution, the drug manufacturer FH Faulding which opened its doors in 1845.

Faulding was acquired by the late serial acquirer Peter Smedley, who merged it into Mayne Group in the hope of creating an integrated logistics and health conglomerate.

Well, that one worked a treat - not - and the injectables side was hived off to global group Hospira.

The oral drug side morphed into Halcygen Pharmaceuticals, which listed in June 2007 on the back of two licensed anti-fungal and antibiotic 'super generics'.

Halcygen was put together by its executive chair Dr Roger Aston, with the enthusiastic backing of pokies king Bruce Mathieson and former Woolworths chief Roger Corbett, and changed its name to Mayne Pharma in November 2010.

In 2016 the company transformed itself by buying Teva's generics portfolio in 2016, which delivered no fewer than 20 oral contraceptives. The purchase was funded by a \$888 million rights issue and placement.

Mayne bought the popular acne generic Doryx in 2015.

To this day, Mayne's business is based at Faulding's Salisbury facility although it also has a factory at Greenville in North Carolina.

Pregnant with promise

Mayne has an expanding women's health portfolio with 27 drugs in development, but its flagship product Nextstellis is by far the most important.

At first blush, contraceptive pills are not exciting, given they've been around for decades.

Nextstellis is based on a novel drug called E4/DSRP. E4 refers not to ethanol content, but to estetrol which is a natural estrogen produced by the foetal liver during pregnancy. The DSRP refers to drospirenone (progestin).

Nextstellis is claimed to have better efficacy and safety, such as bleeding control, relative to other estrogen-based alternatives.

In April 2021, the US Food and Drug Administration approved Nexstellis and it was launched in June 2021 - the first estrogen-based prophylactic launched there in 50 years.

In November 2021, Australia's Therapeutic Goods Administration (TGA) followed suit, with a launch expected in mid-2022.

The US contraceptives market is worth around \$US4 billion and here it's worth about \$125 million a year.

... or delayed development?

Management is happy with initial Nextstellis sales, given Covid-related interruptions which had - at one stage - knocked out almost one third of its sales team.

So far, 1,200 US doctors have written 10,000 prescriptions, with an estimated 5,000 women using the product. Mayne's 70-strong Nextstellis sales team has fielded 80,000 calls and fronted up to 900 educational lunches.

On a four-week rolling basis, prescriptions are up 27 percent.

On the insurance side, 70 percent of patients have some coverage and five percent have unrestricted coverage

“We are confident market access will further improve and be on par with other branded contraceptives in the market,” Mr Richards says.

He says that with 10 million US women using short-acting contraceptives, the market is significant.

The performance of Nextstellis will become more evident after the launch of a pending ‘direct to consumer’ campaign. Advertising prescription drugs is legal in the US and patients often nominate their preferred brand to their doctor (who normally acquiesces, apparently).

Under my skin

Mayne Pharma’s US portfolio consists of nine of the 15 most prescribed molecules by dermatologists to treat a “range of conditions”.

During the six months to December 31, the company launched eight new products, including a generic version of the acne treatment Absorica (isotretinoin).

A further three have been launched in the current year, with a total addressable market of \$US450 million. These include Aczone (dapsons) for acne and Protopic (tacrolimus) for atopic dermatitis (eczema).

In February 2022, Mayne launched an unnamed authorized generic acne treatment with “one of the largest dermatology companies” to distribute in non-retail channels.

Mayne also has a generic version of Kerydin (tavaborole) in the US, to treat onychomycosis - fungus - of the toenails.

In May last year, the company launched a generic version of Sorilux (calcipotriene) foam, for plaque psoriasis. A month later Mayne licensed generics of Solaraze (diclofenac sodium, aka Voltaren) gel for solar keratoses and Actikerall (fluorouracil and salicylic acid) for actinic keratoses.

Finances and performance

Mayne posted a reported loss of \$50.4 million, an improvement on the previous \$181 million deficit. Revenue declined six percent to \$196.4 million, but excluding retail generics turnover would have been 20 percent higher.

The deficit continues a run of red ink: the company lost \$208 million in the year to June 30, 2021 and had deficits of \$92.8 million and \$279 million in the 2019-'20 and 2018-'19 years respectively.

The 'official' first-half loss was dragged down by the aforementioned Nextstellis adjustment, the effects of the pandemic, the cost of start-up investments and adverse payer (insurance) coverage trends.

Underlying earnings before interest tax depreciation and amortization (Ebitda) came in at \$23.7 million, down 38 percent.

In line with recent trends, retail generics accounted for only 20 percent of gross profit, down from 23 percent a year ago and 54 percent three years ago.

Dermatology chipped in 38 percent compared with 34 percent a year and 24 percent three years ago - more than a skin-deep contribution.

The US-based Metrics Contract Services accounted for a hefty 28 percent of gross profit.

As per tradition, management has not proffered a full-year forecast, but the company is not expected to be profitable in the current (second) half.

Mr Richards says management is looking at all of the company's assets and "exploring ways to unlock value in a non-dilutive manner".

Management is also striving for a "leaner and more focused operating model", including discontinuing uncompetitive products and tidying up inventory.

Mayne shares initially jumped two cents to 24 cents in reaction to the February 25 results, but ended the day flat.

Over the last 12 months, Mayne stock has traded between a mid-April 2021 peak of 51 cents and its current low of 22 cents (for a market capitalization of just under \$400 million).

The stock peaked around \$2.00 in mid-2016.

Dr Boreham's diagnosis:

As highlighted by the struggles of the ASX-listed, US-focused counterpart Acrux Limited, generic drugs are unattractive without a trick or two up one's sleeve.

The first fast-mover into the market might make money once a branded drug comes off patent, but there's nothing to stop other competitors from coming along.

The result is rampant discounting.

Mayne therefore looks to be on the right track in terms of de-emphasizing raw generics in favor of more razzle-dazzle.

But given Mayne's recent history of reported losses we suspect that some investors are getting toey and want to see evidence of a solid turnaround.

The corporate housekeeping on costs and such aside, Mayne's fortunes would seem to hinge on Nextstellis, Nextstellis and Nextstellis

And did we mention Nextstellis?

Despite the slow start, the company still aims for peak annual Nextstellis sales of \$US200 million and expects the drug to be the "leading" US contraceptive brand.

The other thing to watch is what the company does to unlock the value of the Metrics Contract arm.

According to Bell Potter's Mr Hester, this business would be worth "more on a trade sale basis than the group's market capitalization."

If achieved, the firm's vaunted stand-alone valuation of \$675 million for the business would go some way to ameliorating the pain at Mayne.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He suffers from onychomycosis from time to time, but we all know he's a fun-guy anyway.