



Biotech Daily

Friday March 11, 2022

Daily news on ASX-listed biotechnology companies

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- * **DR BOREHAM'S CRUCIBLE: MAYNE PHARMA**
- * **VICTORIA \$3m FOR MEDICAL TECHNOLOGY MANUFACTURERS**
- * **NEUREN: AUSTRALIA NNZ-2591 FOR ANGELMAN TRIAL APPROVED**
- * **MEDIBIO RIGHTS RAISE \$730k OF HOPED-FOR \$3.4m**
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- * **AUSCANN LOSES CFO CHARLES ALTSHULER; NEW CFO WANTED**

MARKET REPORT

The Australian stock market fell 0.94 percent on Friday March 11, 2022, with the ASX200 down 67.2 points to 7,063.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 24 fell and five traded unchanged. All three Big Caps fell.

Cyclopharm was the best, up 15 cents or 10.1 percent to \$1.64, with 27,074 shares traded. Atomo climbed 8.7 percent; Cynata and Uscom were up more than five percent; Compumedics was up 3.2 percent; Actinogen, Dimerix and Opthea rose more than two percent; Kazia and Paradigm were up more than one percent; with Proteomics up by 0.9 percent.

Amplia led the falls, down two cents or 13.3 percent to 13 cents, with 96,701 shares traded. Avita lost 8.5 percent; Immutep, Mesoblast, Polynovo and Pro Medicus shed more than six percent; Clinuvel and Oncosil were down more than five percent; Patrys and Pharmaxis fell four percent or more; Antisense, Emvision, Impedimed, Micro-X and Neuren were down more than three percent; Alcidion, CSL, Genetic Signatures, Imugene, Nanosonics and Prescient shed two percent or more; Cochlear, Resmed and Starpharma were down more than one percent; with Telix, Universal Biosensors and Volpara down by less than one percent.

[DR BOREHAM'S CRUCIBLE: MAYNE PHARMA](#)

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.

Halcygen 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 (dapsone) 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 its 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.

VICTORIA GOVERNMENT

The Victoria Government says the \$3 million Medtech Manufacturing Capability Program has opened, with grants from \$100,000 to \$500,000 available.

A Victoria Government media release said that the grant program would help increase medical technology (medtech) production in Victoria “creating new, high-skill jobs and cementing the State’s reputation as a global leader in healthcare innovation”.

The Government said the program would support businesses to make new products and scale-up production in the state, boosting their ability to turn ideas into products.

The Government said that medical technology was “one of the fastest growing sectors in Victoria’s economy and the program will help it grow even faster”.

The media release said medical technology generated \$21.4 billion in revenue and \$3.5 billion in exports annually.

The Victoria Government said that funding would be offered on a one-for-one matching basis, allowing businesses “to fast-track projects, set-up local manufacturing activities and provide opportunities to partner with other Victorian businesses ... [and] increase Victoria’s advanced manufacturing capability, open hundreds of skilled job opportunities and strengthen the state’s long-term global competitiveness”.

An information session on the program will be held on Wednesday March 16, 2022 at 1pm, with registration at: <https://bit.ly/37mRRSH>.

Applications for the Medtech Manufacturing Capability Program are open until 5pm on Tuesday April 5, 2022.

More information is available at: <https://bit.ly/3CyMdlv>.

NEUREN PHARMACEUTICALS

Neuren says it has Australian ethics approval for a 20-child, 13-week, phase II trial of NNZ-2591 for Angelman syndrome.

Neuren said it had approval to conduct the trial at the Queensland Children’s Hospital, Sydney Children’s Hospital and Melbourne’s Austin Health, with separate research authorizations needed from each site.

The company said the study would assess the safety, tolerability, pharmacokinetics and efficacy of oral NNZ-2591 in patients aged from three years to 17 years.

Neuren said that Angelman syndrome was characterized by severe developmental delay and learning disabilities that were noticeable by the age of six to 12 months.

The company said that children and adults with Angelman syndrome typically had balance issues, motor impairment and could have debilitating seizures.

Neuren said that some individuals never walk, most do not speak and disruptive sleep could be “a serious challenge”.

The company said that individuals with Angelman syndrome had “a normal life expectancy, but they require continuous care and are unable to live independently”.

Neuren said that Angelman syndrome was caused by a loss of function of the UBE3A gene on chromosome 15.

The company said it was awaiting US Food and Drug Administration approvals for investigational new drug applications for phase II trials of NNZ-2591 in Phelan McDermid syndrome and Pitt Hopkins syndrome, and was preparing for phase III development of NNZ-2591 in these disorders as well as Prader-Willi syndrome.

Neuren chief executive officer Jon Pilcher said the Australian approval was an “important step achieved for the first clinical trial of NNZ-2591 in patients and Neuren’s first in Australia”.

Neuren fell 16 cents or 3.8 percent to \$4.02.

MEDIBIO

Medibio says its one-for-three entitlement offer at 0.5 cents a share has raised \$729,449 of a hoped for \$3,435,091.

Last December, Medibio said it hoped to raise \$5.7 million through a \$2.25 million placement at 0.5 cents a share and a \$3.4 million one-for-three rights offer at the same price (BD: Dec 15, 2021).

In January, Medibio said its \$3.4 million rights offer would be underwritten to \$1 million by Perth's CPS Capital Group Pty Ltd, which would have the ability to place the shortfall, for a fee of \$20,000 and six percent of the underwritten \$1 million and any shortfall placed Last week, the company said that it and CPS Capital "mutually agreed that the [underwriting] agreement be terminated in light of the escalation of hostilities between Russia and Ukraine" (BD: Mar 2, 2022).

According to Commsec data, throughout February, Medibio has traded around 0.4 cents a share, falling as low as 0.3 cents a share.

Today, the company said that the shortfall was 541,128,367 shares, worth \$,2705642, which it and CPS Capital would attempt to place over the next three months.

Medibio was unchanged at 0.4 cents with 9.5 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its Emtinb significantly reduces inflammatory cytokines associated with multiple autoimmune diseases, in-vitro.

Neuroscientific did not publish any data from the study, but said the cytokines interleukin-17A (IL17A), IL17F and IL6 were associated with the progressive loss of neurons in multiple sclerosis and Alzheimer's disease, and with multiple autoimmune diseases such as psoriasis, rheumatoid arthritis and ankylosing spondylitis.

The company it said it was finalizing a safety data package for ethics approval for a first-in-human, phase I trial.

Neuroscientific managing-director Matt Liddelow said the "impressive results reinforce the multi-faceted therapeutic potential of Emtinb as a disease-modifying treatment for both multiple sclerosis and Alzheimer's disease".

"While chronic inflammation is central to disease pathology of multiple sclerosis, inflammatory responses are thought to be a secondary cause of neurodegeneration in Alzheimer's disease," Mr Liddelow said.

"Therefore, Emtinb has the potential to positively influence neuro-protection, neuro-regeneration and the inflammatory environment that acts to exacerbate tissue damage in these neuro-degenerative conditions," Mr Liddelow said.

Neuroscientific was unchanged at 28.5 cents.

IQ3 CORP

IQ3 says it has entered voluntary administration today, with the Sydney-based de Vries Tayeh appointed as administrators "to restructure".

IQ3 said it was "working with the administrators to maximise the outcome for all stakeholders" and had requested the ASX continue its suspension from trading during the administration period.

IQ3 last traded at 12 cents.

[ANTEOTECH](#)

Anteo has told the ASX that an update presentation on previously announced activities which it did not consider price sensitive may explain a recent fall.

The ASX said the company's share price fell 7.3 cents or 42.9 percent from an open of 17 cents to a low of 9.7 cents on March 10, 2022 and noted a "significant increase" in the trading volume.

The company said it did "not believe anything material was discussed in the webinar that was not commented on in previous announcements and updates" but that to ensure full market knowledge and disclosure, it would lodge an announcement with a link to the presentation.

In January, Anteo fell 28.6 percent to 22.5 cents on news that the Australia's Therapeutic Goods Administration had requested more data for its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test, with hospital and staffing surges due to the Omicron case load impacting the timeline (BD: Jan 28, 2022).

Anteo fell 1.1 cents or 10.5 percent to 9.4 cents with 196.4 million shares traded.

[NANOSONICS](#)

State Street says it has become a substantial holder in Nanosonics with 20,774,459 shares or 6.88 percent of the company.

The Boston-based State Street said that between November 11, 2021 and February 24, 2022, it bought, sold, transferred, lent and returned shares in more than 500 transactions, including purchases ranging from \$3.99 a share to \$6.45 a share.

Nanosonics fell eight cents or 2.1 percent to \$3.77 with 1.15 million shares traded.

[AUSCANN](#)

Auscann says chief financial officer Charles Altschuler has resigned, effective from April 7, 2022.

Auscann said it would begin the search for a new chief financial officer.

Auscann was unchanged at 6.4 cents.