Biotech Daily

Friday February 7, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MEDICAL DEVELOPMENTS UP 20%;**
- PERCHERON DOWN 12.5%

*** DR BOREHAM'S CRUCIBLE: RESMED**

*** NEUREN RECEIVES $80m DAYBUE PRIORITY REVIEW VOUCHER**

*** NEUREN FDA PHASE III NNZ-2591 PHELAN-MCDERMID MEETING**

*** OPYL SIGNS TRIALKEY AVION CRO DEAL**

*** PETER MAC: 'ORAL COMBO PROLONGS BLOOD CANCER SURVIVAL'**

*** NYRADA PHASE Ia NYR-BI03 TRIAL ETHICS APPROVED**

*** GREGORY GEORGE, G TO THE FOURTH TAKE 19% OF MESOBLAST**

*** ACRUX TO LOSE 10-YEAR M-D MICHAEL KOTSANIS**

*** CAMERON BILLINGSLEY REPLACES SYNTARA CO SEC DAVID MCGARVEY**

MARKET REPORT

The Australian stock market fell 0.11 percent on Friday February 7, 2025, with the ASX200 down 9.3 points to 8,511.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 21 fell, five traded unchanged and one was untraded. All four Big Caps fell.

Medical Developments was the best, up 13.5 cents or 20.3 percent to 80 cents, with 471,171 shares traded. Mesoblast climbed 7.2 percent; Paradigm rose 4.2 percent; 4D Medical and Impedimed were up more than three percent; Imugene and Medadvisor rose more than two percent; Amplia, Aroa, Compumedics, Immutep and Universal Biosensors were up more than one percent; with Neuren up by 0.65 percent.

Percheron led the falls, down 0.1 cents or 12.5 percent to 0.7 cents, with 35.3 million shares traded. Actinogen lost 6.1 percent; Starpharma was down 5.7 percent; Resonance fell 4.8 percent; Alcidion, Avita, Nova Eye and Syntara were down three percent or more; Curvebeam, Cyclopharm, Opthea, Polynovo, Resmed and SDI shed more than two percent; Clarity, Cochlear, CSL, Cynata, Dimerix, EBR, Emvision and Pro Medicus were down one percent or more; with Clinuvel, Orthocell and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: RESMED

By TIM BOREHAM

ASX, NYSE code: RMD (Chess depository interests or CDIs)

Share price: $37.69

CDI equivalents: 1,468,670,290

Market cap: $55.4 billion

Financials (six months to December 31, 2024): revenue $US2,507 million ($A4,036 million) up 11%, net income (earnings) $US684 million - up 32%

December quarter 2024: revenue $US1,282.1 million (up 10%), net income (earnings) $US358.3 million (up 29%), earnings per share $US2.43 (up 29%), dividend per share US53 cents (up 10%), cash $US522 million (up 120%), net debt $US151 million (down 80%).

Chairman and CEO: Michael Farrell

Board: Mr Farrell, Dr Peter Farrell (founder, emeritus chair), Carol Burt, Jan De Witte, Richard Sulpizio, Ron Taylor, Karen Drexler, Harjit Gill, Dr John Hernandez, Dr Desney Tan, Christopher Del Orefice

Identifiable major shareholders (US stock): Vanguard 11.58%, Black Rock Inc 9.4%, management 1.21%

As the chorus trilled in the musical Oklahoma! - the farmer and the cowboy should be friends.

In the case of Resmed, the developers of a new class of anti-obesity drugs look like being far more amiable towards the sleep disorders house than investors had assumed.

A couple of years ago, Resmed shares had been weighed down by the prospect of the glucagon-like peptide1, (GLP-1 or semaglutide) fat-busters being so successful that demand for its obstructive sleep apnoea (OSA) devices, masks and other peripherals would be stymied.

In December last year, the US Food and Drug Administration (FDA) approved Eli Lilly's Zepbound (tirzepatide) as the "first and only prescription medicine for moderate-to-severe OSA in adults with obesity".

But the gist is that even Eli Lilly accepts that along with better diets, Resmed's staple of continuous positive airway pressure (CPAP) therapy is part-and-parcel of combating OSA.

Resmed cites evidence that Zepbound users are more motivated to adopt CPAP and have a better long-term compliance rate (more below).

“We believe [the fat drugs] are activating a whole new population of patients who weren’t in the health care system before,” says Resmed CEO Mick Farrell.

Meanwhile, Resmed last week posted December quarter results which investors shrugged off, but which Mr Farrell dubbed as “incredibly strong”.

If Resmed has hit a growth ceiling – as some investors have suspected recently - the results did not betray any lack of momentum.

As well as managing robust device and mask sales, Resmed is making inroads into digital health (at-home OSA monitoring) and consumer wearables (such as smart watches).

To sleep, perchance to snore (about Resmed)

Obstructive sleep apnoea is a sleep-related breathing disorder characterised by complete or partial collapses of the upper airway during sleep, which can lead to pauses in breathing (apnoea) or shallow breathing (hypopnoea).

It can sometimes be fatal - and we’re not referring to the sufferer’s partner smothering him/her with a pillow.

About one billion citizens globally have sleep apnoea - almost half of them severely - with only 20 percent diagnosed.

A prominent Australian global medical success story, Resmed has been listed since 1999 and has been around since 1989, so is well-known as our second-biggest biotech stock (behind CSL).

Resmed makes devices and cloud-based software to diagnose and treat sleep apnoea (snoring), chronic obstructive pulmonary disease (COPD) and other chronic respiratory ailments.

Resmed has its origins in the 1980s, when Sydney sleep expert Dr Colin Sullivan converted a vacuum cleaner to deal with the deafening snores emitted by dogs with pushed-in faces such as pugs, bulldogs and boxers.

The tech was commercialised in the US by the Baxter Centre for Medical Research and other parties, including the Asthma Foundation and the University of Toronto.

Founded by Dr Peter Farrell, Resmed acquired the rights to the technology in 1989.

Resmed listed on the Nasdaq in 1995 and the ASX in late 1999.

These days, the company is run by his son Michael, while Peter assumes the Rupert Murdoch-esque title of ‘emeritus chair’.

Growing via acquisitions

Via acquisitions, Resmed has expanded aggressively into “connected care” - software that enables the patient to use the devices at home, with data streamed to the clinician.

In October 2022, Resmed acquired German software-as-a-service company Medifox Dan - pronounced ‘darn’ - for around $US1 billion (funded by debt).

Medifox Dan is a leader in the nursing home and home health sectors.

In April 2016, Resmed acquired out-of-hospital software provider Brightree for $US800 million and then snaffled up US aged-care and home-care players Healthcarefirst and Matrixcare in late 2018, for $US126 million and $US750 million, respectively.

In December 2018, Resmed ponied up $US225 million for Propeller Health, a Wisconsin-based asthma and pulmonary ‘connected care’ specialist.

In January 2020, Resmed bought Snapworx, a private software company supporting the re-ordering of medical supplies.

And in an October 2021 acquisitive nightcap, the company bought Ectosense, purveyors of the Nightowl cloud-connected home sleep test.

Strategy blueprint

In November, Resmed outlined its corporate vision of what the company would like to achieve by 2030.

The three pillars are increasing (and differentiating) the core sleep products, expanding into other areas such as COPD and insomnia and driving the digital health business.

In the last 12 months, 147 million people used a Resmed product, including digital health offerings. By 2030, the company targets this number to reach 500 million people.

“We are well positioned to meet and beat those goals,” Mr Farrell says.

In short, Mr Farrell says, Resmed is about developing “the smallest, quietest, most comfortable and connected and most intelligent devices, masks and software”.

In the September quarter, the company launched Airtouch n30i mask, which has a fabric - rather than synthetic - lining.

“We sleep on cotton sheets and have fabric covers on pillows, so why can’t we have a sleep apnoea therapy that is just as comfortable as that?” asks Mr Farrell, rhetorically.

The “latest and greatest” device is Airsense 11, which has a touch screen and other digital enhancements.

Aligning with gadgets and gizmos

Resmed is zeroing in on the consumer electronics companies' increased interest in adding sleep diagnoses to their wearable devices (such as smart watches).

Apple and Samsung recently won FDA approval for OSA monitoring.

The company had a 'digital sleep lounge' at January's Consumer Electronics Show in Las Vegas, the key forum for companies to showcase new gadgets.

Resmed has launched the Kontor head strap, an accessory for Apple Vision Pro to enable sleep and breathing monitoring. Resmed's selling point is that Kontor is more comfortable over the extended wear time that users need.

In September last year, Resmed launched Dawn, an artificial intelligence driven "concierge" tool which delivers instant answers about sleep and health questions.

Mr Farrell says the trend reflects the convergence of medical and consumer technology.

"My personal bet is that other providers of consumer wearable will add OSA sleep detection this year," he says.

"This is a once in a generation opportunity for sleep apnoea awareness."

Fleshing out the anti-obesity drug story

The Zepbound approval was on the back of a 469-patient, multi-site, phase II trial, Surmount-OSA, which showed adults taking the therapy averaged up to 20 percent weight loss.

They also had at least 25 fewer breathing interruptions each hour as they slept (relative to placebo). After one year, half of the patients no longer had OSA symptoms.

Eli Lilly's patient guide emulates the American Academy of Sleep Medicine guidelines, which assert that positive airway pressure devices are "the front line, gold standard" for treating sleep apnoea.

AASM suggests weight-loss drugs may be used as "adjunctive or combination therapy" – and not surprisingly Resmed concurs.

"When someone loses weight, it doesn't change their age or gender or – most importantly - their cranio-facial anatomy," Mr Farrell says.

Resmed has tracked 1.2 million patients who have been prescribed GLP-1 drugs and also use CPAP therapy.

The data shows an "increased propensity" for resupply at two years. Given the high CPAP drop-out rate, this is significant.

It’s not all good. Zepbound is not recommended for use in children and “may cause tumors in the thyroid, including thyroid cancer”.

And couch potatoes beware: the drug should also be used with a reduced-calorie diet and increased physical activity.

Investors may still be wary.

Broker UBS notes Resmed shares gained after a “disappointing (although not failed)” phase III trial result for a separate weight loss drug, Cagrisema, in December 2024.

“This suggests investors are still of the view that what is good for the weight loss sphere is bad for Resmed.”

Finances and performance

Resmed reported revenue of $US2,507 million for the six months to December 31, 2024, up 11 percent.

December quarter revenue came in at $US1,282.1 million (up 10%), with net income (earnings) $US358.3 million (up 29%).

Mr Farrell notes strong demand for Resmed’s Airsense 10 device and the “market leading” Airsense 11.

In the quarter, the company’s gross profit margin increased to 59.2 percent.

Management targets a margin of 59-to-60 percent for the current half year.

The results were fairly consistent across geographies and products. US, Canadian and Latin American sales grew 12 percent, with Europe, Asia and the “rest of the world” advancing 8 percent.

Globally, device and mask sales both improved 11 percent, while in the US both products increased by 12 percent.

Mainly reflecting the Medifox Dan acquisition, in-home monitoring rose eight percent.

The company invests six to seven percent of revenue in research and development ($US300 million to $US350 million a year). “We are an innovation machine,” Mr Farrell says.

Resmed had cash of $US522 million, with $US673 million of gross debt and $US151 million net debt and undrawn facilities of $US1,500 million.

While management is keeping its eye out for bolt-on acquisitions, it’s also embarked on a share buyback program at the rate of $US75 million per quarter.

Over the last year Resmed shares have somnambulated between $26.64 on March 1, 2024 and the January 30, 2025, all-time high of $40.75.

At the height of the semaglutide scare, the shares dipped to $21.50 in late October 2023.

Dr Boreham's diagnosis:

With Resmed on a dream run, the question is: what can upset the growth story?

Coming back to Oklahoma! it looks clear the anti-obesity drugs won't be lassoing Resmed's business.

In the meantime, nearest rival Respironics (Phillips) is hampered by the impact of a 2021 ventilator recall and looks more like a poddy calf than a bull.

Mr Farrell says the company's challenge is to ensure Resmed gets a fair chunk of business from the sleep laboratories and home testing companies as awareness of OSA grows. Sometimes that it easier said than done.

Trump's tariffs?

"We are Trump ready," Mr Farrell declares. "Even if there are tariffs on China, we manufacture in Singapore, Sydney and beyond so none of those will be included."

On the flipside, tariffs may impact rivals who import from China or manufacture in Mexico (including the New Zealand-based Fisher & Paykel Health).

Resmed has 21 billion nights of anonymized patient sleep data to play with, a "treasure trove" of information which bodes well for the company's digital health ambitions.

Despite Resmed's leading OSA presence, Mr Farrell argues the company has tapped only 10 percent of its addressable market across all the related maladies.

"With more than one billion people suffocating from sleep apnoea worldwide, we have a lot of runway in our core markets and it's great we have a couple of megatrends on our side to help," he says.

"The future couldn't be brighter".

That may be true. But as they say in athletic circles, if you want to stay number one you have to train like you are number two.

That said, Resmed shows no sign of dozing on the job.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He believes he does not snore, but his partner's opinion sharply differs.

NEUREN PHARMACEUTICALS

Neuren says it has received its one-third share of the $US150 million ($A238.6 million) sale of the Daybue rare pediatric disease priority review voucher by Acadia, in cash.
In 2023, Neuren said that North America partner Acadia Pharmaceuticals had US Food and Drug Administration approval for Daybue, or trofinetide, for Rett syndrome in adults and children two years of age and older (BD: Mar 13, 2023).
Last year, the company said it expected one-third of the proceeds from Acadia's $US150 million sale of the Daybue priority review voucher (BD: Nov 6, 2024).
Neuren was up nine cents or 0.65 percent to $14.02 with 427,389 shares traded.

NEUREN PHARMACEUTICALS

Neuren says it will have a type C meeting with the US Food and Drug Administration to discuss the endpoints of its phase III trial of NNZ-2591 for Phelan-McDermid syndrome.
In 2023, Neuren said an 18-child, phase II trial of NNZ-2591 for Phelan-McDermid syndrome showed a statistically significant improvement (BD: Dec 18, 2023).
Last year, the company said the FDA had granted NNZ-2591 rare paediatric disease designation for Phelan-McDermid syndrome; and later, said it had "aligned" with the FDA at a type B meeting on aspects of a phase III trial (BD: Jul 19, Oct 7, 2024).
Today, Neuren said the type C meeting was considered by the FDA as the best forum for completion of the remaining efficacy endpoints discussion and would "take place face-to-face in early April".
Neuren managing-director Jon Pilcher said the company looked "forward to another constructive discussion with FDA".
"Having a confirmed type C meeting now establishes a clear timetable and in parallel we are continuing all our preparations, planning for mid-year commencement of the first ever phase II trial for children with Phelan-McDermid syndrome," Mr Pilcher said.

OPYL

Opyl says it will provide Melbourne contract research organization (CRO) Avion trial design reports for $5,000 each, using its artificial intelligence (A.I.)-based Trialkey.
Opyl said its Trialkey platform provided "optimized trial design with A.I.-powered analytics, improved site selection and participant recruitment strategies [as well as] comprehensive, actionable reporting for enhanced decision-making".
The company said both parties would work to "to ensure seamless integration of the Trialkey platform into Avion's operations".
Opyl said there were no material conditions that needed to be satisfied for the contract, there was no minimum number of reports commissioned under the agreement and that there was no other material information relevant to assessing the impact of the agreement with Avion on the price or value of the its shares.
Opyl chief technology officer Damon Rasheed said that the partnership was "a testament to the growing demand for Trialkey across the [Asia Pacific] region and beyond".
"Our continued collaborations with respected [contract research organizations], like Avion, demonstrate the industry's confidence in our platform and its potential to transform clinical trials," Mr Rasheed said.
"Together, we're driving a shift toward data-driven strategies that deliver faster, more efficient, and higher-quality trial outcomes," Mr Rasheed said.
Opyl was unchanged at 1.5 cents.

PETER MACCALLUM CANCER CENTRE

The Peter MacCallum Cancer Centre says a triple combination oral tablet, including venetoclax, has led to “significantly prolonged progression free survival” in blood cancer.
The Peter MacCallum Cancer Centre said the 867-patient, randomized, open-label, phase III trial compared acalabrutinib and venetoclax, with or without obinutuzumab, as an oral tablet to chemo-immuno-therapy for chronic lymphocytic leukaemia.
The Centre said the 291-patient acalabrutinib and venetoclax cohort had 36-month progression free survival rate of 76.5 percent and the 286-patient triple combination group had an 83.1 percent progression-free survival rate, with a 36-month progression free survival rate in the chemo-immuno-therapy group of 66.5 percent (p = 0.004).
In 2017, the Walter and Eliza Hall Institute said its researchers had co-discovered venetoclax in a collaboration with Abbvie and Roche’s Genentech (BD: Jul 27, 2017).
A year later, the Peter MacCallum Centre and Royal Melbourne Hospital said a 389-patient, phase III trial found an oral tablet of venetoclax with rituximab more than doubled the likelihood that chronic lymphocytic leukaemia patients would live for two years without their cancer recurring (BD: Apr 5, 2018).
Today, the Centre said the research paper, titled “Fixed-Duration Acalabrutinib Combinations in Untreated Chronic Lymphocytic Leukemia” was published in the New England Journal of Medicine, with the full article available at: https://bit.ly/4aRRlsn.
The study concluded that acalabrutinib and venetoclax, with or without obinutuzumab, “significantly prolonged progression-free survival as compared with chemo-immuno-therapy in fit patients with previously untreated [chronic lymphocytic leukaemia]”.
The Peter MacCallum Centre haematology director Prof John Seymour said another all-tablet approach in chronic lymphocytic leukaemia using ibrutinib was approved in Australia but was “associated with a concerning risk of heart complications which are much less frequent with the acalabrutinib [and] venetoclax combination”.
“Our study indicates a new treatment combination of two or three targeted therapies … can significantly prolong progression free survival compared to the previous standard chemotherapy treatment regimens,” Prof Seymour said.
“These results are very encouraging with the overall survival at 36 months being significantly better with this all-tablet combination compared to chemotherapy treatments,” Prof Seymour said.
The Peter MacCallum Cancer Centre said that “standard chemotherapy treatments for [chronic lymphocytic leukaemia], plus the immunotherapy treatment rituximab, require patients to undergo a lengthy infusion and can cause prolonged immune suppression and other unpleasant side-effects”.

NYRADA INC

Nyrada says it has human research ethics approval to begin its 40-volunteer, phase Ia trial of intra-venous NYR-BI03 for traumatic brain injury and stroke.
Last year, Nyrada said it had completed its pre-clinical studies and expected the phase I trial of NYR-BI03 for traumatic brain injury and stroke to begin in 2024 (BD: Oct 16, 2024).
Today, Nyrada said the double-blind, randomized, placebo-controlled trial would evaluate the safety and tolerability of NYR-Bi03 in health human volunteers, with recruitment to begin shortly and first dosing expected “by the end of March 2025”.
The company said the dose-escalating trial would include five cohorts of eight participants, each, receiving intravenous doses over three hours of either NYR-BI03 or placebo, with six active and two placebo participants per cohort, and results expected by October 2025.
Nyrada was up 0.9 cents or 11.8 percent to 8.5 cents.

MESOBLAST

Gregory George and G to the Fourth Investments say they have increased their Mesoblast holding from 206,719,319 shares (18.10%) to 243,495,998 shares (19.13%).
The Tampa, Florida-based Mr George said the shareholders included James Goerge, Grant George, Citicorp and JP Morgan; and that the shares were acquired between December 15, 2024 and February 4, 2025, with the single largest purchase 2,400,000 shares on February 4 for $4,756,327, or $1.98 a share.
Mesoblast was up 21 cents or 7.2 percent to $3.13 with 7.5 million shares traded.

ACRUX

Acrux says managing-director Michael Kotsanis for more than 10 years has announced his decision to retire, effective on the appointment of a successor.
In 2014, Acrux said it appointed Mr Kotsanis as its chief executive officer and managing-director (BD: Jul 25, 2014).
Today, the company said it had begun a search for a replacement chief executive officer, who would “lead the next phase of the company’s development and growth”.
Acrux chair Ross Dobinson thanked Mr Kotsanis for “successfully developing and implementing the company’s generic drug strategy”.
Acrux was up 0.1 cents or 3.2 percent to 3.2 cents with 716 shares traded.

SYNTARA

Syntara says Cameron Billingsley will replace company secretary David McGarvey, who “has notified the board of his resignation”, effective from today.
Last year, Syntara said Tim Luscombe replaced Mr McGarvey as its chief financial officer, with Mr McGarvey continuing as company secretary (BD: Aug 16, 2024).
Today, the company thanked Mr McGarvey “for his significant contribution to the company for more than 20 years”.
Syntara fell 0.3 cents or 3.85 percent to 7.5 cents with 3.8 million shares traded.