

Biotech Daily

Friday February 5, 2021

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market climbed 1.11 percent on Friday February 5, 2021, with the ASX200 up 75.0 points to 6,840.5 points. Twenty-seven of the Biotech Daily Top 40 stocks were up, six fell and seven traded unchanged. All three Big Caps were up.

Actinogen was the best, up 0.6 cents or 28.6 percent to 2.7 cents, with 283.2 million shares traded. Parys climbed 11.1 percent; LBT was up 9.5 percent; Impedimed improved eight percent; Antisense and Paradigm were up more than seven percent; Cynata and Nanosonics climbed more than six percent; Prescient, Starpharma and Telix were up five percent or more; Nova, Orthocell and Proteomics were up more than four percent; Amplia, Kazia, Mesoblast and Neuren were up more than three percent; Opthea rose 2.2 percent; Cochlear, Compumedics, Imugene, Medical Developments and Pharmaxis were up one percent or more; with Clinuvel, CSL, Polynovo, Pro Medicus, Resmed and Volpara up by less than one percent.

Osprey led the falls, down 0.1 cents or 4.55 percent to 2.1 cents, with 2.8 million shares traded. Uscom lost 3.2 percent; Genetic Signatures shed 2.1 percent; Avita was down 1.1 percent; with Cyclopharm and Next Science down by less than one percent.

DR BOREHAM'S CRUCIBLE: RESMED

By TIM BOREHAM

ASX code: RMD (Chess depository interests or CDIs*)

New York Stock Exchange code: RMD

Share price: \$26.70; Market cap: \$38.85 billion

Shares on issue: 1,455,079,340 (CDI equivalents)

Financials (December 2020 first half):** revenue \$US1,552 million (up 9.5%), net income \$US391.8m (up 26%), earnings per share \$US2.68 (up 25%), cash of \$US256 million, debt of \$US826 million, net debt \$US570m

* Ten CDIs are the equivalent of one NYSE ordinary share

** Non-GAAP (generally agreed accounting principles) measure is used, which adjusts for items such as amortization of acquired intangible assets and restructuring expenses.

Chief executive officer: Michael Farrell

Board: Dr Peter Farrell (founder and chairman), Michael Farrell, Carol Burt, Jan De Witte, Richard Sulpizio, Ron Taylor, Karen Drexler, Harjit Gill

Identifiable major shareholders (US stock): Vanguard 10.3%, Black Rock Inc 6%, WCM Investment Management 6%, SSgA Funds Management Inc 4.5%, Capital Research and Management 3.6%, Fidelity Management 3%.

When it came to the revenue opportunities presented by the coronavirus, the sleep disorders house wasn't caught napping during the "once in a century respiratory medical pandemic".

Used to power its continuous positive airway pressure (CPAP) therapy units, Resmed's ventilators were ideal for Covid-19 sufferers with mild to severe breathing difficulties.

So, the business shift was not so much a full-on pivot for the company, as a gentle sideways shuffle.

History shows that Resmed enjoyed a bumper March and June quarter last year, as coronavirus related ventilator sales more than compensated for a decline in new patients seeking sleep therapy.

"Clearly 2020 was an unprecedented year for companies across every industry and there was much suffering around the world," says Resmed chief Mick Farrell (son of founder Peter). "But we see some blessings: we were able to be there during the emergency and provide 150,000 of them where they were needed."

Hearteningly, Resmed's December quarter (and December half) results released last week show the company is managing a return to more stable conditions, with half year revenue and income increasing 10 percent and 27 percent respectively.

Yes - the virus still rages in the US and Europe. But the company reports that ventilator demand from hospitals has now "largely been met". As we will discuss, Covid-19 impacted Resmed in multiple unexpected ways - some positive and some negative.

Resmed: a tireless growth story

Resmed evolved from the first CPAP machine invented in 1980 by Sydney sleep expert Dr Colin Sullivan. Believe it or not, the crude device was based on a converted vacuum cleaner and was intended to quash the deafening snores of certain dogs.

CPAPs deliver pressurized air through a nasal mask to prevent the collapse of the upper airway - and thus snoring - during sleep.

These days, management's narrative is about digital health: home-based care, based on internet monitoring of sleep behavior.

Resmed sells in 140 countries - either directly or via distributors - and employs 7,500 "Resmedians" (that's "staff" to you and me). Still, the restless US market accounts for just over half of revenue.

The company is also super keen on emerging Asian markets and geographies such as Germany, where reimbursement trends are favorable.

Covid sales become a non e-vent

In the early stages of the pandemic, Resmed pledged to triple its ventilator ('vent') output and ended up producing 150,000 in the June half, a 350 percent increase.

(The company notes that it's not so much about ramping-up production as having the distribution networks that ensure the devices are getting to the right places).

In the June quarter, Resmed chalked up a revenue benefit of \$US35 million (\$A45 million), peaking at \$US124 million in the June quarter and then abating to \$US42 million in the September stanza. In this context, investors were heartened that Resmed managed to increase its overall device sales by five percent, while demand for masks and other peripherals rose nine percent.

Mr Farrell says Resmed's overall sales have been restored to 70 to 90 percent of pre pandemic levels in the US and 80 to 90 percent in Germany (reflecting broader European patterns).

In China - where the sharpest declines were seen – patronage has returned to 70 to 75 percent of pre pestilence levels.

The virtues of The Virus

The plague has also produced some unexpected benefits for Resmed, in terms of increasing awareness of "respiratory hygiene".

This resulted in improved adherence (clients actually using the CPAP contraptions) and increased re-ordering of masks, tubing and humidifiers.

"It's a complex equation and we are working through the variables," Mr Farrell says.

He says in the early stages of the pandemic, some patients feared using CPAP machines would pump more viruses into the room.

Unlike the one about Covid being engineered by Bill Gates - with possible help from the whole Jewish diaspora and space lasers - this one was quashed as fake news.

Mr Farrell says the crisis also boosted the awareness and adoption of remote patient screening diagnosis as well as remote patient monitoring and management.

In other words: digital health.

"We have seen this crisis deliver the importance of healthcare outside the hospital," Mr Farrell says. "And that's where Resmed competes for more than 90 percent of its business and where we add value for customers and where we win."

The rise and rise of 'connected care'

Software-as-a-service, or 'connected care' is an emerging - but increasingly material - business for Resmed.

By that, we mean out-of-hospital software that enables the patient to use the devices at home, with data streamed to the clinician.

In the December quarter, software-as-a-service revenue rose six percent to \$92 million and now accounts for 11 percent of total revenue.

Recent acquisitions have extended Resmed's reach to internet-based monitoring of sleep devices, as well as broadening its presence in chronic obstructive pulmonary disease.

Resmed kicked off by acquiring software-as-a-service business Brightree in April 2016 for \$US800 million. The company then gobbled up Healthcarefirst and Matrixcare in late 2018, for \$US126 million and \$US750 million, respectively.

Healthcarefirst provides services to home health and hospice agencies, while Matrixcare provides software to nursing and retirement homes and home-based care providers.

In 2019, Resmed paid \$US225 million for the Wisconsin-based Propeller Health Solutions, which makes sensors to track asthma or chronic obstructive pulmonary disease (COPD) medication usage.

Mr Farrell says there's a more permanent shift to digital healthcare beyond Covid.

"We have also seen national governments including Japan, France and the US adopting models and taking action to accelerate digital health adoption," he says.

"It provides better availability of healthcare, excellent quality care and significantly lower costs for healthcare systems."

Finances and performance

Last October, management guided to a "sequential" increase in demand following the Covid disruptions (such as folk not keeping sleep clinic appointments).

Indeed, a U-shaped - rather than a more violent V-shaped - recovery has transpired.

Resmed's June half revenue surged 10 percent to \$US1,552 million with profit ('net income' to our American friends) soaring 27 percent to \$US367 million.

More reflecting the post-Covid landscape, December quarter revenue gained nine percent to \$US800 million, while profit rose 12 percent to \$US179.5 million.

Management flags "solid high single-digit" revenue growth for the rest of the year, with double-digit profit growth. This is despite lower patient activity "and little or no incremental benefit from ventilator sales".

Meanwhile, Resmed has been reducing its sizeable debt, the result of the aforementioned acquisitive binge.

The company's current net debt of \$US570 million and \$US1.5 billion of untapped facilities means it's well placed for bolt-on purchases.

Alternatively, management hints that the company might resume a shelved share buyback program.

Resmed's ASX-listed shares have traded between \$18.10 and \$30.08 over the last 12 months.

Taking a breather in former growth market

About five years ago, Resmed made some to-do about entering the portable oxygen concentrator (POC) sector: those mobile tanks and masks wheeled around by folk with COPD and other serious respiratory issues.

During the quarter the company quietly closed this fledgling business.

Mr Farrell says the POC market is not as attractive as it used to be, for reimbursement and other reasons.

"We entered the POC market as way to engage with stage two and stage three COPD patients," he says.

"Since then, we acquired Propeller which gave us access to early-stage patients. Of course, we have core non-invasive ventilation and life support ventilation for more severe COPD patients."

The POC closure cost \$13.9 million in "restructuring expenses", but no more imposts are expected and the closure is expected to be immaterial to future revenue and earnings.

Dr Boreham's diagnosis:

If only because Resmed has been around for so long, it's easy to assume the company's growth prospects have peaked.

Until the digital health push, the gains seemed to be eked out by tweaking the mask and pump range, rather like a car-maker dollying up an ageing vehicle model with more cup holders.

The raw stats are that 936 million people globally suffer from sleep apnoea, with a further 380 million afflicted with COPD (the number two killer and third biggest reason for hospitalizations.) A further 340 million suffer asthma.

So that's an addressable market of 1.6 billion, compared with Resmed's customer base of 118 million and a target of servicing 250 million out-of-hospital users by 2025.

Further growth will come from improving adherence among existing patients and deriving revenue from cloud subscriptions - and the eight billion nights of patient data amassed, so far.

We long ago conceded that Resmed was the gift that keeps giving, despite the low compliance rate with CPAP masks and the advent of more sophisticated oral mouthguard-like appliances (a viable alternative for some sleep sufferers and snorers).

If anything, Covid-19 underlined the resilience of its business model, although the stillrampaging virus means business conditions are "dynamic and unpredictable".

On Morgan Stanley's reckoning, Resmed is trading on a current year earnings multiple of 40 times, assuming subdued current year earnings growth.

It's a moot point whether this is excessive, fellow biotech big boys Cochlear and CSL have traded on similar or higher ratios and have always delivered the bacon.

"We get a good night's sleep," Mr Farrell says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Sweet dreams!

CANN GROUP

Melbourne medical marijuana company Cann Group has requested a trading halt pending an announcement "relating to an investigation that the company is undertaking". Trading will resume on February 8, 2021 or on an earlier announcement. Cann Group fell 1.5 cents or 2.2 percent to 66 cents before the trading halt.

ACTINOGEN MEDICAL

Actinogen says Xanamem for Fragile X syndrome has been granted US Food and Drug Administration rare paediatric disease designation.

Actinogen said Fragile X syndrome was a rare genetic disorder, typically diagnosed in children, with life-long symptoms including behavioral problems, severe anxiety, cognitive impairment and disordered sleep.

Actinogen chief executive officer Dr Bill Ketelbey said that the rare paediatric disease designation had significant advantages including "commercial, development and regulatory benefits for the development of Xanamem in [Fragile X syndrome], with priority review designed to increase overall speed to market".

"Additionally, [the] designation includes the potential for the company to receive a second, transferable priority review voucher that holds substantial additional value," Dr Ketelbey said.

The company said that drugs that qualify for rare paediatric disease designation might receive a priority review voucher if approved by the FDA, which could be used for different indications and could be sold, with average voucher sale prices of more than \$US100 million (\$A131.7 million).

Actinogen said it was planning a 'Xanafx' 40-patient, 12-month, phase II study of Xanamem for anxiety, sleep and behavioral problems in adolescents with Fragile X syndrome, which it expected to begin by 2022.

Actinogen was up 0.6 cents or 28.6 percent to 2.7 cents with 283.2 million shares traded.

ORTHOCELL

Orthocell says its Celgro Dental for tissue repair has been recommended for inclusion on the Australian Register of Therapeutic Goods Prostheses List.

Last year, Orthocell said its collagen-based Celgro, or Striate+, had Australian Therapeutic Goods Administration conformity approval for safety and performance in dental bone and tissue regeneration procedures and hoped that Celgro would be approved for the prostheses list by 2022 (BD: Dec 17, 2020).

Today, the company said that the Prosthesis List defined the minimum amount of benefit to be paid by private insurers for the use of Celgro product used in approved dental bone and soft tissue repair procedures.

Orthocell said that with the recommendation it was progressing toward inclusion on the Prosthesis List "ahead of expectations".

Orthocell managing-director Paul Anderson said the recommendation was "a significant milestone for our company that is made possible by our recent Australian TGA approval and clinical data enabling progression towards reimbursement".

Orthocell was up 2.5 cents or 4.7 percent to 55.5 cents with 1.6 million shares traded.

EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says the Western Australia Government has granted \$880,000 to develop its Openly smartphone application for remote health monitoring.

Emyria said the grant was provided through Western Australia's Future Health Research and Innovation Fund as part of an initiative intended "to boost digital health infrastructure ... [and] involve monitoring the vital signs and mental health of at-risk individuals and confirmed Covid-19 individuals".

The company said it would lead a research collaboration with Western Australia's major health services and universities including the Institute for Respiratory Health, the Public Health Emergency Operations Centre and the University of Western Australia.

Emyria managing-director Dr Michael Winlo said the company was "developing digital health and remote monitoring ... to improve the care of patients with unmet needs".

"We focus on the care of complex patients and those with mental health concerns," Dr Winlo said. "These pivotal studies will support the registration of our leading drug candidate EMD-003, targeting unmet needs in psychological distress and the symptoms of anxiety, depression and stress."

Emyria was unchanged at 14 cents with 3.1 million shares traded.

LITTLE GREEN PHARMA

Little Green has requested a trading halt pending an announcement "regarding a material commercial update and a capital raising".

Trading will resume on February 9, 2021 or on an earlier announcement. Little Green last traded at 93.5 cents.

BIONOMICS

Bionomics has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 16.2 percent from a low of 18.5 cents to a high of 21.5 cents today and noted a significant increase in the trading volume. Bionomics closed up five cents or 29.4 percent at 22 cents with 10.6 million shares traded.

CYCLOPHARM

Cyclopharm says it has received \$3,104,709 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Orthocell said the rebate related to expenditure for the year to December 31, 2020. Cyclopharm fell one cent or 0.4 percent to \$2.80.

<u>CYCLOPHARM</u>

Sydney's CVC says it has reduced its substantial shareholding in Cyclopharm from 6,965,868 shares (8.90%) to 6,644,758 shares (7.24%).

CVC said that between February 27, 2020 and January 27, 2021 it bought shares with an average purchase price of 96.7 cents and an average sale price of \$1.51, and on February 1, 2021 was diluted in Cyclopharm's \$30 million placement (BD: Jan 25, 2021).

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