



Biotech Daily

Friday February 11, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ACTINOGEN UP 4%; TELIX DOWN 7%**
- * **DR BOREHAM'S CRUCIBLE: RESMED**
- * **PHARMAXIS H1 REVENUE DOWN 38%, SALES UP 88% TO \$3m, \$8.8m LOSS**
- * **MAYNE LAUNCHES UNNAMED AUTHORIZED GENERIC FOR ACNE**
- * **ADHERIUM FIRST PRODUCTION OF NEW HAILIE SENSOR**
- * **ACTINOGEN COMPLETES XANAMEM DOSE-RANGING COGNITION TRIAL**
- * **IMPEDIMED TRIALS SOZO FOR RENAL FAILURE**
- * **IMMUTEP IMP321 AUSTRALIA PATENT**
- * **CRESO O-T-C MARIJUANA LOZENGE FOR SARS-COV-2**
- * **LUMOS TO RELEASE 8m SHARES FROM VOLUNTARY ESCROW**
- * **LUMOS M-D ROB SAMBURSKY OFF-BOARD TO FOCUS ON CEO ROLE**
- * **JONATHON GUT TO REPLACE IMRICOR CFO LORI MILBRANDT**

MARKET REPORT

The Australian stock market fell 0.98 percent on Friday February 11, 2022, with the ASX200 down 71.2 points to 7,217.3 points. Seven of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and three were untraded.

Actinogen was the best, up 0.5 cents or 4.2 percent to 12.5 cents, with 7.9 million shares traded. Cyclopharm and Patrys climbed more than three percent; Atomo rose 2.6 percent; Emvision and Proteomics were up more than one percent; with Volpara up 0.6 percent.

Telix led the falls, down 51 cents or 7.4 percent to \$6.36, with 1.4 million shares traded. Paradigm lost 6.2 percent; Polynovo retreated 5.7 percent; Clinuvel and Pharmaxis fell more than four percent; Imugene, Neuren, Opthea, Pro Medicus, Resonance and Starpharma lost more than three percent; Amplia, Antisense, Avita, Cochlear, CSL, Dimerix, Kazia, Mesoblast and Micro-X shed two percent or more; Immutep and Medical Developments were down more than one percent; with Nanosonics, Next Science and Resmed down by less than one percent.

[DR BOREHAM'S CRUCIBLE: RESMED](#)

By Tim BOREHAM

ASX, New York Stock Exchange code: RMD (Chess depository interests or CDIs)

Share price: \$33.84

Market cap: \$49.5 billion

Shares on issue*: 1,462,342,440 (CDI equivalents; 10 CDIs to one NYSE share)

Financials (six months to December 31, 2021): revenue \$US1,798.9 million (up 16%), income (earnings) from operations \$US548.4 million (up 12%), net income \$US438.3 million (up 12%), quarterly dividend per share 42 US cents (up 7.7%), cash \$US194.46 million (down 33%), debt \$US680 million (up 4%)

Chief executive officer: Michael Farrell

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

Identifiable major shareholders (US stock): Vanguard 10.25%, WCM Investment Management 6.2%, Black Rock Inc 5.56%, SSgA Funds Management 4.3%, Fidelity Management 2.8%.

Rather like the top men's tennis players given a leg-up after Novak Djokovic was ejected from the country, the sleep and respiratory giant has been conferred a huge advantage because of a rival's woes.

In June last year, sleep apnoea device maker Philips recalled three to four million of its Dream Station devices because of faulty sound muffling, with the directive later extended to 5.2 million devices. Philips initially costed the recall at EUR250 million (\$A395 million); now it's EUR720 million.

Resmed, of course, doesn't wish its rival ill-will, but it's been quick to capitalize on what chief executive Mick Farrell dubs the "almost infinite" potential to gain market share while Philips sorts out the problem.

On the negative side, Resmed is suffering the component supply problems - especially for semi-conductors - that have beset so many other manufacturers. So, the infinite gains may remain - well - infinite.

That said, Resmed reports \$US125 million to \$US145 million (\$A176 million to \$A200 million) of additional revenue from the Philips recall in the December half year.

By the time the year to June 30 is done, the number is expected to be \$US300 million to \$US350 million - roughly nine percent of total revenue.

“The bottom line is we have at least 12 months more of incredible demand for our Resmed products,” Mr Farrell says.

Released in mid-January, Resmed’s December quarter (and first half) numbers were a picture of defiance against the pandemic-related disruptions to both supply and patient flows.

About Resmed

Resmed is a leader in obstructive sleep apnoea (snoring) and other sleep-related respiratory disorders. Along the way, it has expanded into diagnostic products, ventilation and dental devices, portable oxygen concentrators and internet cloud-based services.

Resmed sells in 140 countries - either directly or via distributors - but the US by far is its most important market. Blame Krispy Kreme donuts.

Resmed’s technology is based on the continuous positive airways pressure (CPAP) intellectual property, developed by the Baxter Centre for Medical Research and acquired by Resmed founding father Dr Peter Farrell in 1989. Baxter sold the masks in Australia from 1988.

Until then, a tracheotomy was the standard treatment for chronic snoring and despite the dangerous knife work involved, many patients were willing to be signed up ... by their spouses.

Intriguingly, the CPAP machines evolved from the quixotic efforts of Sydney sleep expert Dr Colin Sullivan, who converted a vacuum cleaner to deal with the deafening snores emitted by dogs with pushed-in faces such as pugs, bulldogs and boxers.

Further dogged work ensued at the Asthma Foundation (in relation to the then rampant sudden infant death syndrome) and the University of Toronto.

Resmed was incorporated as a US company and admitted to the Nasdaq in June 1995. The company then changed its domicile to the New York Stock Exchange and listed its Chess depository instruments on the ASX in November 1999.

Michael Farrell took over from his father Peter as CEO in 2013. Dad remains chair.

Getting acquisitive

Resmed’s growth increasingly is coming from the “connected care” or “software as a service” (SaaS) part of the business. By that we mean out-of-hospital software that enables the patient to use the devices at home, with data streamed to the clinician. The accrued data is used for product development and proving that the devices actually work.

The digital push is reflected in a string of acquisitions, kicking off with the \$US800 million purchase of Brightree in April 2016. Brightree is not a Christmas ornament, but a software as a service provider for out-of-hospital care.

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 the Minnesota-based Matrixcare provides software to more than 15,000 aged care and other home-based providers.

In December 2018, it was 'chocks away, chaps' as Resmed bought Propeller Health, a Wisconsin-based asthma and pulmonary health specialist, for \$US225 million. Propeller markets sensors that attach to an asthma inhaler or a chronic obstructive pulmonary disease (COPD) drug delivery device and pairs with a mobile application to track medication use.

With its acquisitive appetite yet to be sated, in January 2020, Resmed bought Snapworx, a private software company supporting the re-ordering of medical supplies. In the latest - but no doubt not the last - foray, in October last year, Resmed bought Ectosense, purveyors of the Nightowl cloud-connected home sleep test. The acquisition price was not material and thus not disclosed.

'We never sleep so our patients can'

With seven percent of revenue devoted to research and development, Resmed has developed a constant flow of new products, both in its traditional devices'n'masks domain and the brave new digital world.

The "new" traditional products tend to involve tweaks such as the Airfit N30i mask. With this one, the air tube protrudes from the top of the mask, allowing the person to sleep in any position.

In the digital space, Resmed has 'cloud' based products for patients (Myair), physicians (Airview) and the Brightree range for home medical equipment providers.

In Europe, the company launched Airview for high-risk ventilation patients. Apart from monitoring existing patients, the tool also enables early intervention at the first sign of problems. Michael Farrell hopes Airview will become the standard-of-care for ventilation "in the same way as our core apnoea platform has".

For non-fans of CPAP, Resmed sells a \$279 device called the Bongorx, a set of soft silicon seals one bungs up one's nose. The Bongos create back pressure (expiratory positive airway pressure) when a patient breathes out.

You will comply!

A well-known shortcoming of CPAP masks is that while they work well, they don't work at all if they're not used and compliance rates are low. Quasi rival Somnomed (mouthguard type devices) cites research that shows 70 percent of patients discard the requisite pumps and masks within months because they're uncomfortable.

Thanks to the digital 'cloud' devices, management notes that the company is now privy to more than 10 million nights of (de-identified) patient data. This in turn will inform the company's research and development push.

The company cites an 85,000 patient, peer review study showing that patients availing of Myair increased compliance by more than 87 percent. Carried out in conjunction with the French Government medical system, an Alaskan study of 176,000 patients showed a 39 percent decline in mortality when CPAP usage was maintained.

The Covid bit

Resmed was both a winner and loser from the pandemic. On the negative side, sleep clinic traffic dwindled as patients prioritized avoiding the bug over a decent night's kip.

Depending on the geography, patient traffic has bounced back to 85 percent to 100 percent of pre-Covid levels.

Of course, we might not be done with the cheeky virus yet. But Mr Farrell says that with the emergence of remote screening and monitoring, "we expect the impact of new variants to diminish each time".

On the positive side, Resmed benefited from converting CPAP machines to ventilators for use in Covid wards. This side-line generated \$US160 million of additional revenue in the year to June 30, 2020 and a further \$US70 million in 2020-'21, but is now immaterial.

More broadly, Mr Farrell says, the pandemic has highlighted the importance of "respiratory hygiene" and digital monitoring and telehealth.

Finances and performances

Resmed's December quarter revenues rose 12 percent to \$US895 million, with net profit gaining by a similar increment, to \$US202 million. The half-year receipts from customers were up 15.9 percent to another record: \$US1,798,900,000 (\$A2,555,500,000).

Global device revenues surged a record 16 percent, while mask revenues climbed eight percent. Overall, Resmed gleaned 52 percent of its revenue from devices, 37 percent from masks and 11 percent from the digital out-of-hospital category.

The company derived 66 percent of revenue from the Americas, with 11 percent hailing from the software-as-a-service business. These 'cloud' revenues rose eight percent year-on-year. The remaining 35 percent of revenue came from Europe and Asia, which just about covers the rest of the world.

The company is sitting on cash of \$US194 million, which might come in handy for another bolt-on acquisition or two.

Resmed shares hit a record \$40 a share in early September 2021, having traded as low as \$23.38 in mid-March of that year.

After listing on the ASX in 1999 the shares traded at 88 cents, so long-term holders can sleep easily.

Eyes on supplies

The Philips fillip aside, Mr Farrell says the 16 percent surge in device revenue was none too shabby given the component supply crunch.

To ameliorate this, management implored component makers to prioritize healthcare clients over mobile 'phone and electronic vehicle manufacturers (and the like).

Apparently, this appeal to the (corporate) heart was quite successful. Resmed, in turn, shared the love and prioritized its "highest acuity" patients.

The company has also honed its supply chain to enable new suppliers to be verified more quickly.

But with the supply problems unlikely to abate for the next few months, the company has bunged a \$US12 per device supply chain "levy" - a.k.a. a price rise - effective from January 1, 2022.

Dr Boreham's diagnosis:

Despite Resmed's three decades evolution from sleep apnoea pioneer to market gorilla, Mr Farrell describes the sleep and respiratory markets as "chronically underserved".

Resmed cites a global market of 936 million people with mild to severe sleep apnoea - 54 million in the US - with about 80 percent of them undiagnosed and untreated.

Furthermore, there are 380 million chronic obstructive pulmonary disease (COPD) sufferers worldwide and a further 330 million asthma patients.

In the shorter term, the company plans to treat 250 million patients by 2025, compared with 133 million treated over the last 12 months.

"We expect to see pent-up demand as Covid-19 eases," Mr Farrell says. "We expect the [software as a service] business to accelerate in the high single digits by the end of 2022."

While the core of the Resmed business remains the somewhat clunky CPAP machines and disposable masks, the company has consistently grown thanks to seemingly endless product tweaks and - most importantly - the expansion into the 'cloud'.

As for the Philips recall, don't underestimate the effort required by this stricken rival to regain market share.

Unless Resmed management falls asleep at the wheel, this growth trajectory should not abate.

Disclosure: Dr Boreham is not a qualified medical practitioner and can only have uninterrupted dreams of possessing a doctorate of any sort.

PHARMAXIS

Pharmaxis says revenue for the six months to December 31, 2021 fell 37.8 percent to \$8,518,000, with last years' net profit of \$46,000 turned to a loss of \$8,825,000.

Pharmaxis said the previous corresponding period included a \$10.1 million milestone payment from distribution partner the Parma, Italy-based Chiesi Farmaceutici SpA for sales of Bronchitol and Aridol.

The company said that sales of Bronchitol for cystic fibrosis and its Aridol asthma diagnostic for the six months to December 31, 2021 were up 87.8 percent to \$3,086,000. Pharmaxis said diluted loss per share was 0.02 cents, net tangible assets per share rose 150 percent to 0.5 cents, and it had cash and equivalents of \$20,866,000 at December 31, 2021, compared to \$18,249,000 at December 31, 2020.

Pharmaxis fell half a cent or 4.8 percent to 10 cents.

MAYNE PHARMA

Mayne Pharma says it has launched an unnamed authorized generic of one of its largest dermatology products in the US.

Following a search of US Food and Drug Administration and other websites, the unnamed drug appears to be Epiduo Forte or adapalene with benzoyl peroxide for acne, registered to the Fort Worth, Texas-based Galderma Laboratories LP.

Mayne Pharma said it had a licence agreement with "one of the largest dermatology companies to distribute this product in non-retail channels".

The company said that sales of the product were more than \$US250 million (\$A351.2 million) for the year to December 31, 2021.

Mayne Pharma was up half a cent or 1.8 percent to 28.5 cents with 2.55 million shares traded.

ADHERIUM

Adherium says it has produced a Hailie sensor for Symbicort with physiological parameters, for asthma and chronic obstructive pulmonary disease (COPD).

Adherium said that the Hailie for Symbicort was US Food and Drug Administration approved and engineered for use with Astrazeneca's aerosol inhaler and had completed its first production run at its contract manufacturing partner factory.

According to the Monthly index of Medical Supplies (MIMS) Astrazeneca's Symbicort Turbuhaler contains the cortico-steroid budesonide with the beta2-agonist formoterol.

Adherium said that the addition of physiological parameters to the Hailie range of products "enhances the opportunity for remote patient monitoring services".

The company said that the physiological parameters were valuable when managing severe, uncontrolled and difficult to treat asthma and COPD patients.

The company said that the US patient group was estimated to represent a total market of \$US1.5 billion (\$A2.1 billion).

Adherium said that the Hailie for Symbicort was "the first in a series of devices designed to enable physicians and providers to improve patient care and clinical workflow by capturing advanced data supporting patient management and treatment".

Adherium chief technology officer Geoff Feakes said that the "next generation sensors deliver physiological parameters including inhalation duration, inhalation volume and peak inhalation flow in addition to the existing monitoring of device activation timing and frequency".

Adherium was up 0.1 cents or 7.7 percent to 1.4 cents.

ACTINOGEN

Actinogen says it has completed the final patient follow-up visit for its 107 healthy volunteer Xanamia, dose-ranging part A, phase II trial of Xanamem for cognition.

Actinogen said that the randomized, double-blind trial would evaluate 5mg and 10mg Xanamem dosing levels over six weeks compared to placebo.

The company said that the trial would to confirm the minimum effective dose needed to improve cognition.

Actinogen managing-director Dr Steven Gourlay said the trial would “provide a detailed analysis of the cognitive effects and safety of 5mg and 10mg Xanamem dosing levels”.

“Xanamem has the potential to be a novel daily oral therapy for Alzheimer’s Disease and other neurological diseases that could be used alone or in combination with other therapies to help make a difference to the lives of patients and their families living with serious neurological conditions,” Dr Gourlay said.

The company said it expected results from the trial in April 2022.

Actinogen was up half a cent or 4.2 percent to 12.5 cents with 7.9 million shares traded.

IMPEDIMED

Impedimed says it will conduct a 70-patient, observational trial of its Sozo bioimpedance fluid volume system for end-stage renal failure.

Impedimed said the San Diego, California-based Balboa Research SMO and Waltham, Massachusetts’s Frenova Renal Research would conduct the trial.

The company said that the principal investigators were Dr Mark Boiskin and Dr Dylan Steer who were “two industry leading nephrologists ... [who saw] the compelling potential for the Sozo platform to accurately measure and determine the optimal amount of fluid to remove during dialysis”.

The company said that the trial would be held at three Balboa Nephrology and Fresenius Medical Care joint venture dialysis centres, over four weeks and 12 dialysis sessions.

Impedimed said that the goal of the trial is to assess the applicability of the Sozo platform in a dialysis setting and collected data that can be used to refine the protocol for an interventional trial.

Impedimed said that it expected the trial to begin by March and conclude by July 2022.

Impedimed was unchanged at 19 cents.

IMMUTEP

Immutep says the Australia Patent Office has granted a patent for IMP321, eftilagimod alpha or efiti, for cancer and autoimmune disease.

Immutep said that the patent, titled ‘Combined Preparations for the Treatment of Cancer or Infection’ would protect its intellectual property until January 8, 2036.

The company said that the patent claims protected combined therapeutic preparations comprising IMP321 and an anti-programmed death (PD)-1 or anti-PD-L1 antibody.

Immutep said that the patent includes narrower claims drawn to specific combinations of IMP321 with pembrolizumab, nivolumab, avelumab, durvalumab or atezolizumab, for example.

The company said that the claims were also directed to related methods of use in the treatment of cancer.

Immutep fell half a cent or 1.3 percent to 39 cents with 1.4 million shares traded.

[CRESO PHARMA](#)

Creso says it is in the “final stage of development for a new hemp-based lozenge product to treat severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

Creso said that cannabidiolic acid (CBD-A) was a precursor to cannabidiol, “which has shown strong therapeutic benefits with initial data suggesting that it may stop the ... Sars-Cov-2 virus’ spike protein from binding to and infecting a cell”.

The company said that the product would be commercialized and sold as a food supplement in Europe and Latin America by July 2022.

Creso said that “once the new product line is established, the company will take steps to introduce a range of new delivery methods for consumers”.

The company said that development of the product followed a study by Oregon State University “via a chemical screening technique invented by the organization, that highlighted hemp compounds show the ability to prevent the virus that causes Covid-19 from entering human cells”.

Creso said it had “not undertaken any independent studies on the efficacy of its new lozenge product in the treatment of Sars-Cov-2, and therefore makes no therapeutic claims in this regard”.

Creso managing-director William Lay said the company was “confident that the development of this new hemp-flour based lozenge will become the basis ... to launch another strong product range which can be sold across international markets”.

Creso fell 0.3 cents or 3.4 percent to 8.6 cents with 3.05 million shares traded.

[LUMOS DIAGNOSTICS](#)

Lumos says it expects to release 7,823,595 voluntary escrow shares this month, when it publishes its financial report for the six months to December 31, 2021.

Lumos said the release of voluntary escrow shares was expected by February 28, 2022. According to its most recent filing, the company would have 150,776,978 shares available for trading.

Lumos fell 10 cents or 10.6 percent to 84 cents.

[LUMOS DIAGNOSTICS](#)

Lumos says that managing-director Rob Sambursky has resigned from the board, effective from today, to focus on his role as chief executive officer.

[IMRICOR MEDICAL SYSTEMS](#)

Imricor says controller Jonathon Gut will replace 15-year chief financial officer Lori Milbrandt, effective from July 1, 2022.

Imricor said that Mr Gut joined the company in August 2020 as controller and in May 2021 was appointed director of finance, as well.

The company said that Mr Gut had more than 13 years of accounting and finance experience, with 10 years in the medical device industry and previously worked for Galil Medical and Boston Scientific.

Imricor fell one cent or 1.1 percent to 88.5 cents.