Biotech Daily

Friday February 3, 2023

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.62 percent on Friday February 3, 2023, with the ASX200 up 46.5 points to 7,558.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and two were untraded. All three Big Caps were up.

Next Science was the best for the second day in a row, up four cents or 6.8 percent to 62.5 cents, with 55,821 shares traded.

Actinogen climbed 5.5 percent; Cyclopharm improved 4.3 percent; Avita, CSL, Immutep, Micro-X and Starpharma were up more than three percent; Cochlear, Compumedics, Oncosil, Opthea and Pro Medicus rose more than two percent; with Mesoblast, Orthocell, Paradigm, Resmed and Universal Biosensors up by one percent or more.

Nova Eye led the falls, down four cents or 11.3 percent to 24 cents, with 82,522 shares traded. Kazia lost 7.7 percent; Cynata shed six percent; Neuren and Prescient fell four percent or more; Dimerix and Volpara were down more than three percent; Genetic Signatures shed 2.4 percent; Antisense, Atomo, Impedimed, Medical Developments, Nanosonics, Pharmaxis, Polynovo and Telix were down one percent or more; with Clinuvel and Proteomics 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: $32.31

Market cap: $47.5 billion

CDI equivalents on issue: 1,469,094,140 (10 CDIs are equal to one US share)

Financials (six months to December 31, 2022): revenue $US1,984 million (up 10%), net income (earnings) $US466.5 million (up 6%), earnings per share $US3.17 (up 6%)

December quarter 2022: revenue $US1033.7 million (up 16%), net income (earnings) $US224.4 million (up 13%), earnings per share $US1.66 (up 13%), dividend per share 44 US cents (up 5%), cash $US253 million, net debt $US1.55 billion

Chief executive officer (and chairman elect): Michael Farrell

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

Identifiable major shareholders (US stock): Vanguard 11%, Black Rock Inc 9.2%, WCM Investment Management 6.1%

***** $US1 equals $A1.415.

Like its patients, investors in Resmed are sleeping soundly after the global sleep disorders specialist posted a set of rousing December quarter numbers that largely beat the market's expectations.

The San Diego, California-based outfit - which we will continue proudly to call Australian - has also just signed off on its bolt-on acquisition of German business Medifox Dan, its first purchase of an internet 'cloud' based monitoring provider outside the US.

Resmed chief Mick Farrell cites "incredible demand" - not just for the conventional flow generators but newer lines such as cloud-connected devices and sleep diagnostic tools.

But corporate lore goes that nothing goes right all the time. Supply chain problems persist - especially for electronic components - which means Resmed has not been able to capitalize fully on a huge recall from rival sleep apnoea device maker Philips Respironics.

The good news is that these post-pandemic supply problems are abating and the 'business as usual' shingle is out.

"We are confident of meeting all customer demand by the end of 2023," Mr Farrell says.

About Resmed

As everyone knowzzz by now, Resmed is a leader in obstructive sleep apnoea (snoring) and other sleep-related respiratory disorders.

Its core product remains the continuous positive air pressure (CPAP) machine, a portable pump that delivers a steady flow of air to the somnolent user via a tightly-fitted mask. The air pressure acts as a ‘pneumatic splint’ to keep the airways open.

The CPAP devices are the hardware, while the masks and tubes comprise the disposable components.

In recent years, Resmed has expanded into products that diagnose sleep apnoea, both in the clinic and at home. These include internet-connected devices for remote monitoring. Resmed has also made less successful - or at least lower profile - forays into dental devices (sleep apnoea mouthguards) and portable oxygen concentrators.

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

Sleepers, awake!

In the days of yore, the standard-of-care treatment was a tracheotomy - a hole cut surgically into the windpipe. Not surprisingly, this method was considered to be sub-optimal.

A bright spark then devised uvulo-palato-pharyngo-plasty, which involved cutting out excess tissue in the windpipe to streamline the conduit. Not surprisingly, this method was considered to be sub-optimum, as well.

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

During the 1980s, the tech was commercialized 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 right to the technology in 1989. Resmed listed on the Nasdaq in 1995 and the ASX in late 1999 - and the rest is hizzztory.

Michael Farrell took over from his father Peter as CEO in 2013, with Farrell senior remaining chair. But in a “streamlining” measure unveiled last week the company said Farrell junior would also take over as chair and hold both roles, while Peter would take on an “emeritus chair” role.

During the pandemic Resmed turned over its factories to make ventilators for Covid wards. This sideline generated about $US230 million of revenue over two years, but then again, the pandemic kept clients away from sleep clinics in droves.

Growing via acquisition

After not doing much on the acquisitions front for years, Resmed has expanded aggressively into “connected care”: out-of-hospital software that enables the patient to use the devices at home, with data streamed to the clinician.

In October last year, Resmed acquired German software-as-a-service company Medifox Dan – pronounced ‘darn’ – for $US997 million (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 bought Propeller Health, a Wisconsin-based asthma and pulmonary ‘connected care’ specialist, for $US225 million ($A320 million).

In January 2020, Resmed bought Snapworx, a private software company supporting the re-ordering of medical supplies. In October 2021, it acquired Ectosense, purveyors of the Nightowl cloud-connected home sleep test.

Device line-up

Despite Resmed’s acquisition-fuelled diversification, its playbook is about improving its core products so they are easier and more comfortable to use (the compliance rate with CPAP is notoriously low). Key products are the Air Sense CPAP pump range and the Airfit and Air Touch masks. The diagnostic range includes Apnea Link Air and Night Owl.

One example of a tweaked product is the Airfit N30i mask, which is designed with the air tube protruding from the top of the mask, rather than the face. 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.

A key reason for the 16 percent boost in revenue for the quarter was a sizeable increase in production of so-called ‘card-to-cloud’ devices. This refers to Airsense 10 pumps which were re-engineered to circumvent computer chip shortages.

Management’s priority is to increase output of its Airsense 11 devices, which are state-of-the-art in terms of connectivity and usability.

Finances and performance

In the three months to December 31, 2022, Resmed chalked up revenue of $US1033.7 million, 16 percent higher. Net income (we call it profit here) was $US224.4 million, 13 percent to the good.

Resmed’s device revenues surged 20 percent to a record $US542 million, while the masks and accessories sales rose13 percent to $US374 million.

Management highlighted an “extraordinary” 18 percent boost in software-as-a-service (SAAS) revenue, to $US116.8 million. “We see this as the start of the digital health marathon and I can tell you we love the race,” Mr Farrell said.

Overall, Resmed gleaned 52 percent of its revenue from devices and 36 percent from masks, with the digital/SAAS side chipping in steady 11 percent.

The Americas (read: the US) contributed 72 percent of revenue, compared with 65 percent a year previously.

Post the Medifox Dan purchase, Resmed has cash on hand of $US250 million and undrawn debt of $US390 million. In short, the company is well placed for more tuck-in acquisitions.

The company expended $US70 million on research and development, up 12 percent and expects to earmark seven to eight percent of revenue for such exploratory pursuits in the full year.

Resmed shares have held their ground over the last year, trading between $27.37 (late May 2022) and $35.70 (October 2022). The shares hit a record $40 in September 2021.

Five years ago, the stock was worth just over $12.

A Philips fillip?

In June 2021, Philips was forced to withdraw one million of its ventilators from the market because of a problem with sound abatement foam. It was found the disintegrating material created toxic gases.

The trouble is, regulators are less than happy with the replacement foam, which apparently can break off and clog the airpath.

Since then, the number of recalled devices has swollen to 5.5 million and Philips is also mired in a class action from aggrieved users.

The great guessing game within the industry is when Philips will return to market and how it will impact Resmed. But Mr Farrell opines that investors and analysts have been fretting far more than Resmed management, and that Philips’ return to market would “not be a big perturbation”.

Why? When Philips does come back to market, its devices will create demand for Resmed’s masks and peripherals.

Judging from Philips’ quarterly report musings this week, there’s no sign of an imminent return to market. When it does re-enter, the world’s second biggest CPAP player will be competing more with the tier-two players that have bobbed up to fill demand.

“I look forward to them coming back,” Mr Farrell declares. “We have the playbook ready for all scenarios.”

Broker Wilsons goes a step further and assumes the Philips/Respironics business is “irreparably damaged”.

The taxman calleth

Resmed’s annual report - filed to US authorities - reveals a $US238 million settlement to the Australian Taxation Officer, pertaining to a long-running transfer pricing dispute.

Transfer pricing involves the shift of revenue and profits to lower taxing regimes. First announced in October 2021, the settlement stems from the activities of the ATO’s Tax Avoidance Taskforce which also winkled settlements from BHP, Apple, Chevron, Facebook, Google and Microsoft.

Resmed’s gross liability was $US381.7 million, including $US48.1 million in interest and penalties.

Allowing for $US143 million of credits and deductions, the company wrote out a cheque for $US284.8 million. But such are the quirks of accounting the payment did not leave a hole in the latest financials.

Dr Boreham’s diagnosis:

While the Resmed story is well known - as is CPAP treatment generally - Michael Farrell maintains the sleep and respiratory market is “globally under-penetrated.”

As Mr Farrell puts it, close to a billion people “suffocate” every night with mild to severe sleep apnoea, with there are a further 380 million chronic obstructive pulmonary disease (COPD) patients and 330 million asthma patients.

“During calendar 2022, we improved over 149 million lives and we are well on our way to helping 250 million … by 2025,” Mr Farrell says.

To be specific, these envisaged 250 million clients are not all CPAP users, but may avail of a monitoring application or a mask for use with another company’s pump.

Nonetheless, this implies Resmed will continue to increase volume at a compound annual rate of 17 to 18 percent - a decent clip for a mature company.

Given reimbursement remains crucial, we suspect Resmed always will be a US-oriented business.

In the meantime, the Medifox Dan purchase shows that management is not asleep at the wheel and has its eye on growth prospects elsewhere.

Disclosure: Dr Boreham is not a qualified medical practitioner but in his sleepless half-dreaming state can only hope that some sort of said qualification may fall out of his Weet Bix packet one morning

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY

RMIT says its researchers have developed an anti-microbial suture material intended to reduce the incidence of post-operation mesh infections.

RMIT said that its anti-microbial suture material glowed in medical imaging and "could provide a promising alternative for mesh implants and internal stitches".

The Institute said the suture material combined iodine with nanoparticle 'carbon dots', which were inherently fluorescent, due to their particular wavelength, but could be tuned to various levels of luminosity to stand out from surrounding tissue in medical imaging.

RMIT said attaching iodine provided anti-microbial properties and greater x-ray visibility.

The Institute said that laboratory tests on the fluorescent surgical filament was easily visible on CT scans after three weeks when threaded through samples of chicken meat, and killed 99 percent of drug-resistant bacteria after six hours at body temperature.

The research article, titled 'Smart suture with iodine contrasting nanoparticles for computed tomography' was published in Opennano and the full article is available at: https://www.sciencedirect.com/science/article/pii/S2352952022000822?via%3Dihub.

The article concluded that using computed tomography (CT) the "visualization can monitor the wound site, suture degradation and disappearance after the surgery".

"In addition, the developed suture possesses enhanced antimicrobial properties combined with low or suppressed toxicity due to the presence and release of [iodine carbon nanoparticle] over an extended time," the article concluded.

"This slow-release property assists in the prevention of biofilm formation and infection of the suture after the surgery," the research article concluded.

University of Melbourne Prof Justin Yeung said the study addressed a challenge faced by surgeons in trying to identify the precise location of internal meshes on CT scans.

"This mesh will enable us to help with improved identification of the causes of symptoms, reduce the incidence of mesh infections and will help with precise preoperative planning, if there is a need to surgically remove this mesh," Prof Yeung said.

The Institute said the next steps were pre-clinical trials, which had seed funding.

GENETIC TECHNOLOGIES

Genetic Technologies says it will launch a "world first comprehensive risk assessment test" for hereditary, familial and sporadic breast and ovarian cancer.

Genetic Technologies said its test would evaluate "a woman's risk of developing breast and/or ovarian cancer either from a hereditary genetic mutation or from the far more common familial or sporadic cancer".

The company said that "combined with other clinical risk factors the test provides a comprehensive risk assessment in a simple saliva test".

Genetic Technologies said its test would add "the detection of the 13 major actionable breast and ovarian susceptibility genes and to the Genetype test platform".

The company said that there were more than 2.26 million cases of breast cancer and 313,000 cases of ovarian cancer diagnosed each year.

Genetic Technologies said its test would be presented at the BRCA, or breast cancer gene, meeting in Montreal in May 2023, and provide screening for the 85 percent of women diagnosed with breast and ovarian cancer with no hereditary or family history.

Genetic Technologies chief executive officer Simon Morriss said the test was "one of our most important and significant contributions to the advancement of population-based genetic testing".

Genetic Technologies was up 0.4 cents or 133.3 percent to 0.7 cents with 509.65 million shares traded.

THERAPEUTIC GOODS ADMINISTRATION

The Therapeutic Goods Administration says it will allow the prescription of psilocybin and 3,4-methylene-dioxy-meth-amphetamine (MDMA) from July 1, 2023.
The TGA said the two psychedelic drugs could be “prescribed by specifically authorized psychiatrists” and it would permit the prescription of MDMA for post-traumatic stress disorder and psilocybin for treatment-resistant depression.
“These are the only conditions where there is currently sufficient evidence for potential benefits in certain patients,” the TGA said.
The Administration said that prescribing will be limited to psychiatrists, given their specialized qualifications and expertise to diagnose and treat patients with serious mental health conditions, with therapies that are not yet well established.
The TGA said that psychiatrists would need to be approved under the Authorised Prescriber Scheme by the TGA following approval by a human research ethics committee.
The Administration said that the Scheme allowed prescribing permissions to be granted “under strict controls that ensure the safety of patients”.
The TGA said that the decision “acknowledges the current lack of options for patients with specific treatment-resistant mental illnesses” and the change means that psilocybin and MDMA could be used therapeutically in a controlled medical setting.
“However, patients may be vulnerable during psychedelic-assisted psychotherapy, requiring controls to protect these patients,” the Administration said.
The TGA said that for these specific uses, psilocybin and MDMA would be listed as schedule 8 (Controlled Drugs) medicines in the Poisons Standard.
The Administration said that for all other uses, they will remain in schedule 9 (Prohibited Substances) which largely restricts their supply to clinical trials.
The TGA said that the decision followed applications to reclassify the substances in the Poisons Standard, extensive public consultation, a report from an expert panel, and advice received from the Advisory Committee on Medicines Scheduling.
The Administration said there were “currently no approved products containing psilocybin or MDMA that the TGA has evaluated for quality, safety and efficacy, however, this amendment will allow authorized psychiatrists to access and legally supply a specified ’unapproved’ medicine containing these substances to patients under their care for these specific uses”.
More information is available in the psilocybin and MDMA questions and answers at: https://bit.ly/3wSrq0A.

PATRYS

In two separate substantial shareholder notices, Mason Stevens says it has reduced its Patrys holding from 158,735,837 shares (7.72%) to 111,000,699 shares (5.40%).
Mason Stevens said that between April 19, 2022 and January 25, 2023 it bought and sold shares in more than 660 separate transactions.
Patrys was unchanged at 3.1 cents with 5.5 million shares traded.

IMRICOR MEDICAL SYSTEMS

Blackrock Group says it has reduced its substantial holding in Imricor from 11,771,428 shares (8.21%) to 10,734,845 shares (7.09%).
Blackrock said that between June 24, 2022 and February 1, 2023 it sold 1,036,582 shares at prices ranging from 13 cents to 30 cents a share.
Imricor fell two cents or 9.1 percent to 20 cents with 2.1 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Perennial Value Management says it has increased its substantial holding in Lumos from 13,338,882 shares (6.03%) to 15,730,245 shares (7.09%).
The Sydney-based Perennial said that between on January 23 and February 2, 2023 it bought and sold shares with the single largest purchase 1,328,719 shares for $39,949 or three cents a share.
Lumos was unchanged at three cents with 1.1 million shares traded.

CRESO PHARMA, ROOTS SUSTAINABLE AGRICULTURAL TECHNOLOGIES

The Southport Magistrates Court says that the matter involving former Creso executive director and Roots director James Anthony Ellingford, 57, has been adjourned.
Last year Mr Ellingford was bailed on six charges including contravention of a domestic violence order and stalking (BD: Nov 30, 2022).
An officer of the Southport Magistrates Court, on Queensland's Gold Coast, told Biotech Daily at that time that Mr Ellingford appeared before Magistrate Janice Crawford on Friday November 25, 2022 charged with: two counts of contravention of a domestic violence order; one count of unlawful stalking; and three counts of "improper use of emergency call services, vexatious".
Today, the Court told Biotech Daily that the matter had been adjourned to March 1, 2023.
Creso fell 0.1 cents or five percent to 1.9 cents with 21.6 million shares traded.