



Biotech Daily

Friday February 2, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.51 percent on Friday February 2, 2018 with the ASX200 up 31.3 points to 6,121.4 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and four were untraded.

LBT was the best, up one cent or five percent to 21 cents with 23,809 shares traded.

Admedus climbed 4.2 percent; Acrux, Avita, Oncosil and Prana were up more than three percent; Factor Therapeutics and Starpharma rose more than two percent; Reva and Volpara were up more than one percent; with Cochlear, CSL, Nanosonics, Opthea, Pro Medicus and Viralytics up by less than one percent.

Uscom led the falls, down two cents or 9.1 percent to 20 cents with 130,000 shares traded.

Airxpanders, Clinuvel, Medical Developments, Neuren, Osprey and Universal Biosensors lost three percent or more; ITL shed 2.5 percent; Impedimed, Mesoblast, Optiscan, Polynovo and Resmed were down more than one percent; with Ellex down 0.5 percent.

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

By TIM BOREHAM

ASX: RMD (Chess depository interests)

New York Stock Exchange: RMD

Share price: \$12.34

Market cap: \$17.6 billion

Shares on issue: 142,891,971 US shares; 1,428,919,708 CDIs*

Financials (December half): revenue \$US1,125 billion (\$A1,409 billion) (up 13%), operating income \$US258.5 million (up 35%), net income \$US95,651,000 (\$A119,792,200) (down 37%).

(December quarter): revenue \$US601.3 million (up 13%), operating income \$US146 million (up 51%), net income \$US9.5 million (down 88%**), cash \$US858 million (up 9%), dividend per share 35 US cents (up 6%).

Chief executive officer: Michael Farrell

Board: Dr Peter Farrell (founder and chairman), Carol Burt, Dr Gary Pace, Richard Sulpizio, Ron Taylor, John Wareham, Karen Drexler. (Long serving Resmed director and former Cochlear chief Dr Chris Roberts retired at the last AGM)

Identifiable shareholders: Fidelity Management 6.03%

* Ten CDIs are the equivalent of one NYSE ordinary shares

** Reflects \$US119.8m "transitional impact" of US tax cuts and \$US6.7m deferred tax impact.

The sleep disorders house has been listed since 1999 and has been around since 1989, so is well-known as our second-biggest biotech stock (behind CSL and ahead of Cochlear).

A prominent Australian global medical success story, Resmed's reach covers four million patients in 120 countries.

But for the Rip van Winkles among us who have missed it all, here's a quick primer:

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

Obstructive sleep apnoea - bad snoring - is not only hazardous to marriages, but it can be life threatening.

Given the condition is linked to overweight middle-aged men, Resmed gleans about half of its revenue from the US, land of the fat and the free.

Believe it or not, a tracheotomy was the standard treatment for dangerous snoring before continuous pressure air pumps (CPAPs) and masks came along.

Resmed now has access to 1.5 billion nights of respiratory care data - akin to watching the Chinese and Japanese populace combined snoozing for one night - and that makes for a valuable resource for developing new products and arguing for reimbursement.

Awareness of sleep disorders is also growing, while the recovering US economy means more sufferers have the means to do so and not suffer in silence (so to speak).

It wasn't too many sleeps ago that Resmed was feeling the effects of enhanced competition and poor patient compliance, mainly because its sleep masks were uncomfortable and made the user look like Hannibal Lecter on an especially homicidal day.

Judging from the San Diego-based Resmed's December (second) quarter results, the Australian-grown overseas success story has regained its groove, on the back of both new and re-imagined products.

Despite some challenging numbers in the previous corresponding quarter, Resmed globally recorded a nine percent rise in device sales (the air pumps) and a 13 percent increase in mask sales.

Resmed is also tapping the internet cloud software phenomenon, which means clinicians can monitor patients in the comfort of their own beds (the patients' own beds, just to clarify).

"Our masks have performed well around the world, device sales are solid and our cloud based software continues to grow rapidly," chirps CEO Mick Farrell.

Resmed is also winning market share from its key rivals: Philips Respironics, Fisher & Paykel Health, DeVilbiss Healthcare, Apex Medical and BMC Medical. The companies revel in constant patent disputes, with Resmed duking it out with Fisher & Paykel in several tit-for-tat legal actions, globally.

While selling prices remain under pressure - we don't know by what quantum because the company no longer discloses them - Resmed was able to maintain gross margins by increasing "operating leverage".

In layman's terms, that means cutting costs.

Mick Farrell, by the way, took over from old man Peter - the company's founder - in 2013. We have no problem with such nepotism, relatively speaking

Song remains the same (but different)

With apologies to Led Zeppelin, the song remains the same at Resmed, which still gleans most of its revenue from the sleep apnoea market.

But the songbook has tweaked in three ways: improved iterations of old products, a move into the expansive chronic obstructive pulmonary disease (COPD) sector and an expansion into the cloud-connected market.

In early 2016 Resmed acquired Brightree - a software-as-a-service business - for \$US800 million.

Resmed's focus on remote cloud-based monitoring recently won the imprimatur of French authorities, who said 'oui' to reimbursement for telemonitoring of sleep apnoea patients. Not surprisingly, the company is in active conversation with governments and payers (insurers) elsewhere.

"We will get the message through to them that telemonitoring ... improves outcomes and improves lives and we think other countries will follow suit," Mr Farrell says.

Resmed's product suite would do an Apple store proud: new products include Airfit and Airtouch (facial and nasal masks), Airmini (the smallest continuous pressure air pump on market), and Myair (a patient engagement app).

In particular, management calls out the success of the Airfit F20 facial mask as a driver of market share gains. The difference? The mask is made of foam, not plastic and feels more like a comfy pillow.

This quarter Resmed plans to assault the COPD market with its first-own branded portable oxygen compressor unit, the Mobi. The company acquired the Texas-based Inova Labs two years ago.

To date, Resmed has sold Inova's Activox range of compressors.

The COPD market is seen as lucrative because there are 65 million sufferers globally and it's now the third-biggest cause of death, with high rehospitalisation rates.

Let's talk about tax

Much of the second quarter results briefing was devoted to tax reform on both sides of the Pacific. In the US, Trump's famous corporate tax cuts are a reality, while the Bunyip Parliament is expected to pass tougher multinational tax laws any tick of the clock.

While the Trump tax changes are positive overall for Resmed, the measures will play havoc with the company's short term reported numbers. The quarterly numbers recognised an extra tax bill of \$126.6 million, reflecting a transitional tax on unremitted foreign income and the diminished value of residual tax assets.

This resulted in Resmed's 'official' 88 percent plunge in reported earnings.

Excluding the one-offs, the effective tax rate for the quarter was six percent, but is expected to rise to 15-16 percent in the second half and then settle at 21-23 percent in the 2018-'19 year.

But Resmed believes the overall US package will be positive, providing more flexibility to repatriate funds to the US and undertake capital management or acquisitions.

... and the dollar

Currency is an eternal issue and the Aussie dollar chugging above 80 US cents is an unwanted headwind. Resmed, however, reports in greenbacks, so the key translation effect is converting the US dividend to the local lingo.

Philosophical chief financial officer Brett Sandercock says the company has lived with the Aussie being as low as 47 US cents and as high as \$US1.03.

“We just have to live with currencies moving around and have initiatives in place to counteract that,” he says. For example, manufacturing is now done in Singapore as well as Australia and the company deploys the usual currency hedging instruments.

Dr Boreham's diagnosis:

While expansive, the sleep disorders market is heavily competed, not just by the pump-and-mask brigade but the likes of Somnomed, which makes a bespoke mouthguard for sleep apnoea at a fraction of the price.

And who can forget Rhinomed's Mute plastic nose clips to keep the nostrils open: \$24.99 for three at all good pharmacies (for a while, Resmed was selling the Mutes on its online store).

Given the alternatives, Resmed management thus deserves credit for maintaining sales revenue off a \$US2.2 billion a year global sales base.

Over the last year, Resmed shares have meandered between \$9 and the post-results record \$12.66. While the results were well-received, not everyone's a fan given the company trades on a meaty earnings multiple of around 28 times.

This year, Resmed will spend \$40.6 million on R&D - almost seven percent of revenue.

Given that chunky spend, a steady flow of new devices (and tweaked old ones) should ensure sweet dreams for investors and patients alike.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He also does not snore, but admittedly has not stayed awake to check.

ADMEDUS

Admedus says that the launch of its first, shaped, tissue product, Cardiocel 3D in North America “marks a significant milestone for Admedus ... and our Adapt technology”.

Admedus said in a media release, not published on its ASX platform, that the Cardiocel 3D treated bovine heart tissue was a “unique, pre-shaped curve [providing] physicians immediate access to a clinically-superior, off-the-shelf, optimized arch reconstruction [product] with non-antigenic response and unique calcification resistance”.

In November, Admedus said it expected the North American Cardiocel 3D launch to be February 1, 2018, following US regulatory approval in April (BD: May 2, Nov 14, 2017).

In May, Admedus responded to an ASX ‘aware’ query that its Cardiocel 3D grant by the FDA was not material, with the ASX noting a four cent or 12.3 percent share price rise from 32.5 cents on April 28 to 36.5 cents on May 1, 2017 and that the US Food and Drug Administration had granted Cardiocel 3D 510(k) pre-market approval on April 28, but the company did not announce the approval until May 2, 2017.

The ASX said companies were required to make material announcements immediately.

In the media release, Admedus chief executive officer Wayne Paterson said that Cardiocel 3D was “a disruptive technology in the high-complexity congenital defect repair space”.

“Surgeons can achieve a more natural shape, allowing for optimal compliance and dynamics, while simultaneously providing the superior clinical benefits of our Adapt technology to deliver transformative healing,” Mr Paterson said.

“The launch of Cardiocel 3D in North America is also an exciting commercial opportunity for Admedus as we continue to move up the value chain, building momentum and credibility as a bankable medical technology business,” Mr Paterson said.

Admedus said in the media release that to support the launch, its representatives participated in the Thoracic Surgeons Meeting in Florida from January 27 to 31, 2018 where they introduced Cardiocel 3D and discuss the growing body of evidence that shape mattered in complex arch repair with cardiothoracic surgeons.

Admedus was up one cent or 4.2 percent to 25 cents.

ITL HEALTH GROUP

ITL says that wholly owned subsidiary Myhealthtest Pty Ltd has launched a prostate specific antigen (PSA) test for men to monitor their PSA level from home.

ITL said that it was the fourth Myhealthtest direct-to-consumer pathology test following launches of its the diabetes, thyroid and cholesterol test services.

The company said that the four test services were being marketed to addressable markets worth more than \$1 billion.

ITL said that prostate cancer was the most common cancer diagnosed in Australia and the third most common cause of cancer death, with one in six men diagnosed with prostate cancer by the age of 85 years.

The company said that the PSA blood test measured proteins made by both normal and cancerous prostate cells and while a raised PSA level was not a diagnosis of cancer, the test could be used as an indicator of a potential problem.

ITL said that because PSA levels could vary, doctors used results from several tests over time to help determine the risk of prostate cancer.

The company said the prostate test was available through the Myhealthtest online shop and would be promoted to its existing database, new customers and health care providers through promotional campaigns, with immediate effect.

ITL fell one cent or 2.5 percent to 39 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it will take a 10 percent stake in Adelaide clinical services specialist CPR Pharma Services for 4,000,000 Proteomics shares.

The company said that deemed value of the shares would be the 30-day volume-weighted average price to the CPR shareholder approval and at today's closing price would be about \$1.2 million.

Proteomics said the two companies would partner "to offer an advanced suite of services to improve drug development in clinical trials".

The company said that the partnership had "the potential to speed up drug development, saving biopharma companies millions of research dollars".

Proteomics said that CPR had more than 80 staff, with multi-million dollar revenue from clients in the US, Asia, Europe and Australia

The company said it would provide its predictive diagnostics and analytical services capability to complement CPR as a regional provider of clinical services and laboratory testing in clinical trials.

Proteomics managing-director Dr Richard Lipscombe said the alliance "presents a fantastic opportunity to expand our diagnostics portfolio and grow revenue".

Proteomics said that the acquisition was subject to CPR shareholder approval by February 28, 2018 with the transaction due to be completed by March 5, 2018.

Proteomics said that it could elect to take a second share swap of four million shares for a further 10 percent of CPR.

Proteomics fell half a cent or 1.6 percent to 30 cents.

ALCIDION GROUP

Alcidion says it has completed the \$NZ3 million Oncall Systems acquisition for its clinical messaging and mobile task management systems for hospitals and healthcare.

In December, Alcidion said that the Auckland, New Zealand-based Oncall had designed Smartpage, a clinical communications suite that comprised three software modules for clinical, orderly and emergency messaging and tasking delivered through the internet "cloud" and it would pay Oncall an upfront payment of \$NZ750,000 (\$A681,087) with a second component capped at of \$NZ2,250,000 with 40 percent cash and 60 percent in scrip (BD: Dec 7, 2017).

Alcidion was unchanged at 4.7 cents.

BARD1 LIFE SCIENCES

Bard1 says that the Japan Patent Office has issued a patent providing additional protection for prevention or treatment of lung and colorectal cancer.

Bard1 said that the patent protected the sequence of various Bard1 isoforms specific to lung and colorectal cancer, a method for detecting the presence of the specific Bard1 isoforms and a method for treating and/or preventing lung cancer and colorectal cancer.

The company said the issued patent, entitled 'BARD1 isoforms in lung and colorectal cancer and use thereof', provided additional protection until August 17, 2031 over the parent case for modulators such as small interfering RNA (siRNA) molecules of specific Bard1 isoforms for use in treatment or prevention of lung or colorectal cancer.

Bard1 said the patent was filed in the name of the Université De Genève and the Hôpitaux Universitaires de Genève, from whom it had licenced the rights to the technology.

Bard1 was up 0.1 cents or 9.1 percent to 1.2 cents with 94.5 million shares traded.

[BTC HEALTH \(FORMERLY BIOTECH CAPITAL\)](#)

BTC says that its wholly owned subsidiary BTC Speciality Health's Perisolv dental gel has been included in the Australian Register of Therapeutic Goods.

BTC said that the Conformité Européenne (CE) mark approved Perisolv was a biochemically active gel that optimized the treatment of periodontitis, mucositis and peri-implantitis.

The company said it expected Perisolv to be available in Australia by July 2018.

BTC said that when the gel was applied directly to the periodontal pocket it exerted a bacteriostatic effect and aided in dissolving degenerated tissue making the debridement easier for both dental professionals and patients.

BTC executive chairman Dr Richard Treagus said that Perisolv was the second of three products licenced from RLS Global AB.

Last month BTC said that Carisolv gel for dental caries had been confirmed for inclusion in the Australian Register of Therapeutic Goods (BD: Jan 21, 2018).

BTC was untraded at 20 cents.