



Biotech Daily

Friday February 17, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: BENITEC UP 8%, OPTHEA DOWN 7%**
- * **DR BOREHAM'S CRUCIBLE: RESAPP**
- * **VICTORIA PROVIDES \$32m FOR CANCER TRIALS, RESEARCH**
- * **PRO MEDICUS H1 REVENUE UP 6% TO \$15m, PROFIT UP 63% TO \$5m**
- * **ITL H1 REVENUE UP 11% TO \$17.5m, PROFIT UP 103% TO \$2m**
- * **BIONOMICS H1 REVENUE DOWN 30% to \$7m, LOSS EVEN AT \$10m**
- * **PHARMAXIS H1 REVENUE DOWN 26% to \$7m, LOSS DOWN 1% TO \$11m**
- * **POLYNOVO WINS FIRST SOUTH AFRICAN BTM ORDER**
- * **FRANCE PAYS \$17k PER SIRTEX TREATMENT; VESPRO PROTOCOL**
- * **MEMPHASYS, PRIME DISPUTE GF100 BLOOD SEPARATOR**
- * **LLOYDS & CASSANOVE SELLS CYCLOPHARM 18% TO NEIGHBOR CHURCH**
- * **SIMON BUCKINGHAM REPLACES ADMEDUS DIRECTOR MICHAEL BENNETT**
- * **BIO-MELBOURNE 'NEW KIDS ON THE STOCK' EXCHANGE BRIEFING**

MARKET REPORT

The Australian stock market fell 0.18 percent on Friday February 17, 2017 with the ASX200 down 10.5 points to 5,805.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and six were untraded. All three Big Caps fell.

Benitec was the best, up 1.5 cents or 8.1 percent to 20 cents with 635,207 shares traded. Factor Therapeutics climbed 6.6 percent; Clinuvel and Ellex were up more than five percent; Living Cell was up 4.8 percent; Pharmaxis improved 3.45 percent; Anteo, Genetic Signatures and Polynovo rose two percent or more; with Impedimed, Oncosil and Orthocell up more than one percent.

Opthea led the falls, down six cents or 6.6 percent to 85.5 cents with 275,563 shares traded. Pro Medicus fell 4.3 percent; Osprey lost 3.4 percent; Atcor, Bionomics, Cochlear, Mesoblast and Viralytics shed more than two percent; Acrux, Admedus, Airxpanders, Compumedics, CSL, Neuren and Starpharma were down more than one percent; with Medical Developments, Nanosonics, Resmed and Sirtex down by less than one percent.

[DR BOREHAM'S CRUCIBLE: RESAPP HEALTH](#)

By TIM BOREHAM

ASX code: RAP; **Market cap:** \$215m; **Share price:** 35.5c

Chief executive officer: Tony Keating

Board: Dr Roger Aston (chairman), Tony Keating, Brian Leedman, Chris Ntoumenopoulos.

Financials: December 2016 quarter cash burn of \$1.147million (year to date \$1.83 million). Cash of \$12.17 million at December 31, 2016.

Major shareholders: Freeman Road (6.8%), Fidelity International (6%).

The developers of the world's first clinically proven, smart-phone based respiratory disease diagnostic faces its stiffest test not from the regulators, but from the Screen Actors Guild.

After all, if coughing into an app becomes the global standard of care for respiratory diagnosis, how do producers of medical dramas portray the next crop of Marcus Welby MDs without a stethoscope draped around their neck?

Clutching a mobile doesn't confer the same medical credibility, white coat or not.

Auscultation – the art of listening to a chest to ascertain the diseases within – has been practised for 2000 years. Stethoscopes have been around for 200 years.

The trouble is, it's a notoriously unreliable instrument, prone to considerable operator error.

According to Resapp director and co-founder Brian Leedman, general practitioners get it wrong in about 25 percent of cases, although hospital-based diagnoses are more accurate than that.

The Resapp algorithm was invented by the University of Queensland's Prof Udantha Abeyratne, originally with a sleep apnoea focus.

As is the wont with medical technology the focus changed, in this case to detecting chest diseases purely from the sound of the cough.

With a grant from the Bill and Melinda Gates Foundation, the application eventually emerged from the laboratory and into Resapp which back-door listed in July 2015.

Globally, more than 700 million patients visit their docs for respiratory disease annually (including six to eight million in Australia) and they are frequently misdiagnosed.

As experienced chest listeners would attest, a cough is not a cough: pneumonia, asthma, bronchiolitis and upper tract infections all emit different patterns, as does chronic obstructive pulmonary disease (COPD) in adults, not to mention heart failure causing fine crackles at the bases of the lungs.

The Bill and Melinda show funded a 2013 paediatric study at Indonesia's Sardijto Hospital, with 91 patients involved.

This was followed up by a 976-patient study (also paediatric) at Perth's Joondalup Health Campus and Princess Margaret Hospital.

While enrolments and analysis of the Perth study are on-going, the initial results have been, well, breath-taking.

For instance, the device diagnosed bronchiolitis with 100 percent accuracy and pneumonia and asthma with 97 percent and 95 percent accuracy.

The clever app could even distinguish between asthma and pneumonia 90 percent of the time.

This was followed up by a 772-patient adult study with accuracy rates of 98 to 100 percent (COPD, pneumonia, upper respiratory tract infection) and 88 percent (pneumonia versus asthma).

The company has now launched Smartcough-C, a pivotal US paediatric study at three confirmed sites: Massachusetts General Hospital, Texas Children's Hospital and Cleveland Clinic.

The primary endpoint of the double-blinded study is diagnosis of childhood pneumonia, with the secondary endpoints of diagnosis of upper respiratory tract infection, croup, bronchiolitis, asthma and viral wheeze and "lower respiratory tract involvement".

Recruitment is expected by the end of March, with analysis in the June quarter.

If all goes well, Resapp plans to file a new device submission to the FDA for approval as a class two medical device - one that assists doctors in their diagnosis, not as a stand-alone at-home tool.

PROSPECTS:

A key revenue opportunity for Resapp lies with the expansion of telehealth, web based consultations for which a stethoscope (or imaging and blood tests) is irrelevant.

Accounting house Deloitte estimates 75 million virtual consultations take place in the US alone and Goldman Sachs estimates this addressable market at \$US12 billion.

Around 30 to 50 percent of these consultations are for respiratory disease, in which case all the provider can do is suggest the patient see a real physician.

Stockbroker Patersons recently initiated coverage on Resapp with a target price of 59c a share.

The firm forecasts a \$6 million loss this year, swinging to a 2017-'18 profit of \$13 million and earnings in 2018-'19 of \$36 million.

According to Patersons, a typical doctor's visit in the US costs \$US200.

Virtual consultations range from \$US40-50, with the telehealth provider typically pocketing \$US10.

According to Mr Leedman, telehealth is only one path to market.

It's quite possible that Resapp could become the global standard of care for general practitioners, in which case stethoscopes will be banished to the props room of the BBC's period drama department.

DR BOREHAM'S VERDICT:

We would like to declare Resapp as one of the sector's untapped value plays.

But we can't.

The shares, which relisted in July 2015 after a \$4 million capital raise at 2c apiece, soared to a high of 53c last September.

Have investors expectorated too much of the folding stuff?

Perhaps.

But management has lived up to its promises to date, which contrasts Resapp with similarly hyped 'wheezeometer' asthma detection play Isona (now batting on as Respiro, ASX code RSH).

Despite the reduced burden of proof to get a device to market, Resapp's regulatory and marketing timelines look ambitious in our view.

Dr Boreham would not rush to buy the shares at current levels.

But stethoscope wielders beware, this one looks like coughing up the goods.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He does not own a stethoscope and nor is he a licensed financial adviser.

VICTORIA GOVERNMENT

The Victoria Government says it will provide \$20 million over four years to the Victorian Comprehensive Cancer Centre for clinical trials and \$12.2 million for cancer research. A media release from Health Minister Jill Hennessy said the research projects were funded through the Victorian Cancer Agency.

Ms Hennessy's media release said that clinical trials were "vital for advancing cancer breakthroughs by testing the latest treatments, drugs and medical devices that can deliver even better patient outcomes and save lives" and the funding would ensure more patients could take part in trials, including those in rural and regional Victoria.

The media release said that the Victorian Cancer Agency grants were "fast-tracking the conversion of research into clinical practice" and included the first Allied Health and Nursing Clinical Research Fellowship.

The media release said the projects included: \$2,200,000 over 36 months to the Olivia Newton-John Cancer Research Institute, La Trobe University, Austin Health, Monash Health, Peter MacCallum Cancer Centre and the University of Melbourne for 'Development of a novel combined radiotherapy immunotherapy approach in patients with diffuse large B cell lymphoma';

\$2,250,000 over 36 months to the Peter MacCallum, the University of Melbourne Olivia Newton-John Cancer Wellness and Research Centre, Alfred Hospital, Eastern Health, Border Medical Oncology, Melbourne Melanoma Project Consumer Reference Group, and the Walter and Eliza Hall Institute for 'Novel approaches for overcoming resistance to therapies for advanced melanoma';

\$1,600,000 over 36 months to Peter MacCallum, the University of Melbourne, Monash University, Austin Health, Monash Medical Centre, Calvary Mater Newcastle, Chris O'Brien Lifehouse and the Garvan Institute for 'Combination of radionuclide ¹⁷⁷Lu-PSMA therapy with pembrolizumab in patients with metastatic castration-resistant prostate cancer'; and

\$1,500,000 over 36 months to Monash University, Royal Melbourne Hospital, Peter MacCallum, Murdoch Children's Research Institute and Alfred Health for 'The International Acute Myeloid Leukaemia Platform Consortium'.

The University of Melbourne's Dr Catherine Granger won the Victorian Cancer Agency Allied Health and Nursing Clinical Research Fellowship for the 'Cancer and Physical Activity (Capacity) Trial: Implementation of a self-management program in the lung cancer model of care'.

WEHI's Prof Clare Scott was awarded a fellowship for 'Pre-clinical models of ovarian cancer sub-types and other rare cancers to enable new therapeutic approaches'.

The Peter MacCallum's Dr Nicholas Clemons won a fellowship for 'A new paradigm for targeting mutant p53 tumours', with Dr Charbel Darido awarded a fellowship for 'Novel therapeutic approaches against squamous cell carcinoma of the head and neck'.

Monash University's Dr Luc Furic won a fellowship for 'Targeting MYC driven prostate cancer by combining targeted radionuclide therapy with ribosome biogenesis inhibition as a new therapy in castration resistant prostate cancer and neuroendocrine prostate cancer'.

La Trobe University's Dr Belinda Parker won a fellowship, for 'Using immune markers to individualise therapy for patients with triple negative breast cancer';

WEHI's Dr Tracy Putoczki won a fellowship for 'A new therapeutic opportunity to improve patient response to current treatments for colorectal and pancreatic cancers', with Dr Sarah Best taking an early career grant for 'Pre-clinical investigation of non-small cell lung cancer'; while Peter MacCallum's Dr Laura MacPherson won an early career grant for 'Understanding the role of HDAC-3 in acute myeloid leukaemia stem cell survival'.

PRO MEDICUS

Pro Medicus says revenue for the six months to December 31, 2016, was up 6.4 percent to \$15,202,000 with net profit after tax up 63.1 percent to \$4,796,000.

Pro Medicus said it would pay an unfranked 1.5 cents a share dividend for investors at the record date of March 10, to be paid on March 24, 2017.

The company said it “continued to make strong inroads into the North America market winning a \$18.0 million contract with Mayo Clinic ... made significant progress with its installations with all key implementations being on or ahead of schedule” while the European business “performed in line with expectations” and the Australian business improved as a result of increased adoption of the Visage products, with its promedicus.net electronic-health site continuing to perform well

The company said that net tangible assets per security was up 31.25 percent to 21 cents, with diluted earnings per share up 61.75 percent to 4.61 cents at December 31, 2016.

Pro Medicus said it had cash and cash equivalents of \$20,278,000 compared to \$16,190,00 at December 31, 2015.

Pro Medicus fell 20 cents or 4.3 percent to \$4.44 with 489,285 shares traded.

ITL

ITL says revenue for the six months to December 31, 2015, was up 10.6 percent to \$17,474,000 with the net profit after tax up 102.8 percent to \$2,117,000.

ITL said it would not pay an interim dividend.

The company said its Australia healthcare division revenue was up four percent primarily due to price and margin improvement measures, while biomedical revenue was up 27 percent due to improved market conditions in the US, volume growth from new product sales and increased sales to healthcare.

The company said that net tangible asset backing per share was up 6.1 percent to 10.4 cents at December 31, 2016, while diluted earnings per share was up 83.3 percent from 1.2 cents to 2.2 cents.

ITL said that cash and cash equivalents was \$1,371,000 at December 31, 2016 compared to \$611,000 at June 30, 2016.

ITL was up 7.5 cents or 17.9 percent to 49.5 cents with 2.8 million shares traded.

BIONOMICS

Bionomics says that revenue for the six months to December 31, 2016, fell 30.1 percent to \$7,136,513 with net loss after tax up 0.06 percent to \$9,696,734.

Bionomics said that revenue included licence fees, collaboration income, royalties, sales income, rental and interest income received as a result of ordinary activities, with other income from government grants and assistance including the Research and Development Tax Incentive and other forms of income.

The company said that diluted loss per share increased 57.1 percent to 2.2 cents for the six months to December 31, 2015 and net tangible asset backing per share fell 35.4 percent from 8.2 cents at December 31, 2015 to 5.3 cents at December 31, 2016.

Bionomics said it had cash and cash equivalents of \$43,122,288 at December 31, 2016 compared to \$51,407,979 at December 31, 2015.

Bionomics fell one cent or 2.6 percent to 37.5 cents.

PHARMAXIS

Pharmaxis says that revenue for the six months to December 31, 2016, fell 26.3 percent to \$6,910, 000 with net loss after tax down 1.3 percent to \$11,035,000.

Pharmaxis said revenue came from sales of Bronchitol for cystic fibrosis as well as the Aridol test for bronchial hyper-responsiveness.

Pharmaxis said that diluted loss per share fell 25 percent from 0.04 cents in the previous year to 0.03 cents for the six months to December 31, 2016, with net tangible assets per share down 59.5 percent to 3.2 cents and cash and cash equivalents of \$29,245,000 at December 31, 2016, compared to \$45,936,000 at December 31, 2015.

Pharmaxis was up one cent or 3.45 percent to 30 cents.

POLYNOVO

Polynovo says it has its first undisclosed South African order for its biodegradable temporising matrix (BTM) wound treatment.

Polynovo said the order covered all BTM sizes and enabled South African distributor Surgical Innovations to supply product directly to hospitals and surgeons.

The company said that trauma, burns and reconstructive surgery in South Africa was a “significant opportunity for the use of BTM”, with US sales expected in the “near future”.

Polynovo was up half a cent or two percent to 25.5 cents.

SIRTEX MEDICAL

Sirtex says France has agreed to full reimbursement for SIR-Spheres for colorectal liver metastases patients who failed on, or are intolerant to, prior chemotherapy.

Sirtex said that the French Ministry of Health based its decision on clinical evidence of the efficacy and safety of SIR-Spheres for treating the patient population and agreed to provide reimbursement, believed to be about EUR12,600 (\$A17,438) per treatment.

Sirtex interim chief executive officer Nigel Lange said the “granting of reimbursement in France is specific to SIR-Spheres Y-90 resin microspheres in refractory metastatic colorectal cancer and highlights the accepted evidence of clinical benefit for patients who have had their cancer progress despite systemic chemotherapy treatments”.

Sirtex said that reimbursement was specific to SIR-Spheres and Mr Lange said that the company expected an increase in dose sales.

The company said France had about 41,000 colorectal cancer cases in 2012, the third most common cause of cancer mortality, accounting for about 17,000 deaths each year.

Sirtex said France had a universal healthcare government-managed system with more than 95 percent of the population covered by health insurance.

Separately, Sirtex said the meta-analysis protocol for the Sarah and Sirvenib studies had been published in the Journal of Medical Internet Research Research Protocols.

Sirtex said the combined prospective meta-analysis of the European 459-patient ‘Sorafenib versus radioembolisation in advanced hepatocellular carcinoma’ (Sarah) trial and the 360-patient Asian ‘Sirt versus sorafenib’ (Sirvenib) trial was known as Vespro.

Sirtex said that both studies were directly comparing SIR-Spheres yttrium-90 resin microspheres with sorafenib, and had “the effect of providing this meta-analysis with the advantages of a single, large, randomized study of 819 patients”.

The company said it expected to publish the two trial results separately and together with the combined meta-analysis, which was expected by the end of 2017.

The protocol is available at: <http://www.researchprotocols.org/2017/2/e17/>.

Sirtex fell six cents or 0.4 percent to \$15.11 with 453,670 shares traded.

MEMPHASYS

Memphasys says that following the set aside of a dispute with Prime Biologics Pte Ltd it is hoping to negotiate settlement of a dispute over a blood separation machine.

This week Memphasys said it agreed with Prime to set aside legal proceedings over the \$S4,821,623 (A4,424,437) dispute (BD: Feb 15, 2016).

Today, the company said that a further remaining court action continued in relation to the GF100 blood separation machine which Memphasys said it rented to Prime but Prime was now claiming to own (BD: May 17, 2016).

Memphasys said it was awaiting the outcome of its application for summary judgement against Prime and had attempted to resolve all disputes through negotiated settlement.

The company said it had filed an application for arbitration in Singapore to hear and resolve the dispute between Memphasys, Prime Biologics and Manukan over the \$S4,821,623 debt associated with the fit-out of the Prime rental facility in Singapore, the value of the B class shares in Prime and the enforceability of the option agreement.

Memphasys was unchanged at 0.4 cents with 1.3 million shares traded.

CYCLOPHARM

The London-based Lloyds & Cassanove Investment Partners has sold its 10,568,470 Cyclopharm shares (17.69%) to the Anglo Australian Christian and Charitable Fund.

Both companies give their addresses as 65 St Paul's Churchyard, London.

In 2013, Lloyds & Cassanove said it increased its holding in Cyclopharm to 10,186,974 shares (17.7%) (BD: May 3, 2013).

In today's filing, it appeared that Lloyds & Cassanove counted 381,496 shares purchased between May 2 and August 28, 2013 twice.

The company said it sold 10,568,470 shares for \$9,617,308 or 91 cents a share.

In 2013, Lloyds & Cassanove said it acquired 469,374 shares for \$72,406 or an average price of 15.4 cents a share.

The Anglo Australian Christian and Charitable Fund said it bought 10,568,470 shares for \$9,617,308.

Cyclopharm was untraded at 91 cents.

ADMEDUS

Admedus says Michael Bennett has resigned as an executive director and will be replaced by Simon Buckingham as a non-executive director, effective 17 February 2017.

Admedus executive chairman Wayne Paterson said the company expressed "its gratitude to Mr Bennett for the contributions he has made ... over the past 12 years".

The company said that Mr Buckingham had more than 25 years' experience in the pharmaceutical industry and was currently an advisor to the Allschwil, Switzerland-based Actelion and a director of Actelion Australia.

Admedus said that Mr Buckingham had been Actelion's North America and Asia-Pacific head, responsible for commercial operations in the region and prior to Actelion he worked in sales and marketing for Parke-Davis in the US and Roche, in Switzerland and Australia. The company said that Mr Buckingham was currently a director of Pharmaxis, Creso Pharma, Vaxxilon AG and Actelion.

Admedus said that Mr Buckingham held a Bachelor of Veterinary Science degree from the University of Sydney, a Doctorate of Philosophy from the University of Melbourne, and a graduate management qualification from the University of New South Wales.

Admedus fell half a cent or 1.5 percent to 32 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its February 28, 2017 briefing will address the process of listing on the Australian Securities Exchange.

The Network said it was “reaching out to biotechnology, medical technology and pharmaceutical companies who are in the process of listing or considering listing on the Australian Securities Exchange” for the ‘New Kids on the Stock’ briefing.

The Network said that Dimerix chief executive officer Kathy Harrison and Noxopharm investor relations manager Prue Kelly would speak about their respective organisations’ experience in becoming listed companies.

The Bio-Melbourne Network said that Hive Legal principal Simon Davidson would discuss insights that he gained leading the team assisting Adalta with its initial public offer, which raised \$10million.

The Network said that ASX Melbourne listings manager James Gerraty, whose team facilitate new listings and secondary capital raisings, would address managing relationships with listed Victoria-based entities.

The Network said that the panel would provide an overview of the process and then take part in a discussion covering intellectual property, company structure, legal due diligence, timelines and the importance of internal compared with external expertise.

The Bio-Briefing will be held at KPMG, Tower 2, 727 Collins Street, Melbourne on February 28, 2017, with registration from 4.15pm, presentations until 5.30pm and then networking until 6.30pm.

To register go to: <http://bit.do/newkidsonstock>.