



Biotech Daily

Monday August 13, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRANA UP 7%; COMPUMEDICS DOWN 25%**
- * **VALE BARD1'S PROF GEOFF LAURENT: 23.2.1948 – 12.8.2018**
- * **FDA CLEARS GI DYNAMICS US ENDOBARRIER RE-START**
- * **NHMRC, MRFF, FEDERAL \$200m FOR 337 RESEARCH PROJECTS**
- * **SLOAN KETTERING STARTS TELIX KIT PROSTATE IMAGING TRIAL**
- * **COMPUMEDICS, HEALTH 100 JV 'UNEXPECTED COMPLEXITIES' DELAY**
- * **COGSTATE REVENUE UP 10% TO \$40m, LOSS DOWN 12% TO \$778k**
- * **UNIVERSAL BIO H1 REVENUE UP 6% TO \$13.5m, PROFIT TO LOSS**
- * **MICRO-X EXPECTS UNQUANTIFIED XINRAY IMPAIRMENT CHARGE**
- * **CYNATA LENDS DR ROSS MACDONALD, DR STEWART WASHER \$1.8m**
- * **ADMEDUS FURTHER EXTENDS CAPITAL RAISING SUSPENSION**
- * **VISIONEERING TECHNOLOGIES REQUESTS 'CAPITAL RAISING' HALT**
- * **MERCHANT GROUP TAKES 8.1% OF RHYTHM**
- * **MACQUARIE GROUP TAKES 6.2% OF IMPEDIMED**
- * **THORNEY TAKES 12% OF TPI**
- * **MEDICINES AUSTRALIA APPOINTS DR ANNA LAVELLE CHAIR**
- * **MMJ: MEDIPHARM APPOINTS SYBIL TAYLOR, MICHAEL PERRON**

MARKET REPORT

The Australian stock market fell 0.42 percent on Monday August 13, 2018 with the ASX200 down 26.2 points to 6,252.2 points. Seven of the Biotech Daily Top 40 stocks were up, 25 fell, six traded unchanged and two were untraded.

Prana was the best, up 0.3 cents or seven percent to 4.6 cents with 139,859 shares traded. ITL climbed 5.6 percent; Cyclopharm was up 4.65 percent; Telix and Uscom rose more than three percent; with Cochlear, Medical Developments, Nanosonics and Resmed up less than one percent.

Compumedics led the falls, down 14.5 cents or 24.8 percent to 44 cents with one million shares traded. Prescient lost 13.3 percent; Factor fell 8.2 percent; Airxpanders retreated 7.1 percent; Imugene, Neuren, Oncosil and Optiscan shed five percent or more; Ellex, Impedimed, LBT and Opthea fell four percent or more; Mesoblast was down 3.2 percent; Avita, Benitec, Clinuvel, Pro Medicus and Volpara shed more than two percent; with Bionomics, Genetic Signatures, Orthocell and Osprey down more than one percent.

BARD1 LIFE SCIENCES

Bard1 says non-executive director Prof Geoffrey Laurent died suddenly, yesterday, August 12, 2018.

Bard1 chairman Peter Gunzburg said the company was “deeply shocked and saddened by this unexpected event”.

“Geoff was a leading respiratory scientist and highly respected member of the Bard1 board who made an invaluable contribution to the strategic direction of the company since his appointment in 2016,” Mr Gunzburg said.

“It was an honor to know Geoff personally and work with him on the Bard1 board,” Mr Gunzburg said.

According to his ASX profile Prof Laurent was an editor, advisory board member and scientist with more than 250 peer-reviewed publications.

The ASX said that Prof Laurent was an emeritus professor at the University of Western Australia, a scientific advisor and consultant at Helmholtz Zentrum Munchen and from 2012 until 2017, the director of the Institute for Respiratory Health and the director of the Centre for Cell Therapy and Regenerative Medicine at the University of Western Australia. The ASX said that Prof Laurent was previously the director of the Centre for Respiratory Research, vice-dean of enterprise and head of the research at University College London’s Department of Internal Medicine.

The profile said that Prof Laurent was the editor-in-chief of the International Journal of Biochemistry and Cell Biology, a past president of the British Association for Lung Research and was a visiting scientist at Johnson & Johnson.

Bard1 was unchanged at 1.3 cents.

GI DYNAMICS

GI Dynamics says the US Food and Drug Administration has approved a trial of its Endobarrier duodenum insert for obesity and type 2 diabetes.

In 2015, GI Dynamics closed a planned 500-patient US trial, with five of the 325 enrolled patients developing bacterial liver infections (BD: Mar 6, May 6, Jul 30, 2015).

In 2017, the European Union withdrew the Endobarrier conformity certificate and in 2016 the Australian Therapeutic Goods Administration cancelled the Endobarrier approval (BD: Sep 14, Oct 24, 2016; May 18, Nov 13, 2017).

Today, GI Dynamics said the first stage of the trial would assess 50 patients to be treated with Endobarrier and 17 control patients.

The company said that once the first stage patients reached the six-month post-implantation follow-up it would submit a safety report to the FDA, which if approved would allow it to expand the trial’s enrolment of a further 130 Endobarrier patients and 43 controls, taking the total enrolment to 240 patients.

GI Dynamics said the trial’s primary endpoint was a reduction in average HbA1C, or blood-sugar levels, after one year of treatment

The company said specific safety events would stop enrolment, including: hepatic abscess requiring any procedure other than image-guided fine needle aspiration or oral antibiotics; three hepatic abscesses that required oral antibiotics; one instance of device-related bleeding requiring transfusion, embolization or intensive care unit care, and three instances of endoscopic intervention that included cauterization or endoscopic clipping of a bleeding lesion.

GI Dynamics said that, subject to securing additional finance, it expected to complete stage one enrolment by July 2019.

GI Dynamics was up 0.3 cents or 12 percent to 2.8 cents.

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL FEDERAL GOVERNMENT, MEDICAL RESEARCH FUTURE FUND

The Federal Government says the National Health and Medical Research Council and Medical Research Future Fund will provide \$200 million for 337 research projects. A media release from the Minister for Health Greg Hunt said the NHMRC would provide \$192 million for 320 projects and the Medical Research Future Fund would provide \$7.4 million for 17 grants, with a full list of projects available at: <https://beta.nhmrc.gov.au/funding/data-research/outcomes-funding-rounds>.

TELIX PHARMACEUTICALS

Telix says the first two of 500 patients have been imaged in a phase II prostate cancer imaging trial using its 68Ga-PSMA-11 at the Memorial Sloan Kettering Cancer Centre. Telix said it was supporting the New York-based Sloan Kettering study by providing access to kits for the preparation of the prostate cancer imaging agent 68 Gallium-labeled prostate-specific membrane antigen 11 (68Ga-PSMA-11).

The company said it had partnered with the Liege, Belgium-based Advanced Nuclear Medicine Ingredients (ANMI) SA to develop the kit for the US, including submission of a drug master file to the US Food and Drug Administration (BD: Jul 25, 2018).

Telix said it had collaborated with Sloan Kettering during the past three months to validate the use of the kits at the hospital's radio-pharmacy service, with Sloan Kettering amending its investigational new drug application to enable the use of the kit in the study.

The company said that it benefitted from both Sloan Kettering opening the drug master file for FDA review, as well as "early adopter feedback and timely user feedback".

Telix chief executive officer Dr Christian Behrenbruch said that there were "very few places in the US that are better to polish a product prior to wider launch".

Telix US president Dr Bernard Lambert said the company was "grateful for the collaboration with [Sloan Kettering] and the valuable product development insights we have gained from working with one of America's most vibrant oncology-focused radio-pharmacy services".

Sloan Kettering radiochemistry and imaging sciences service chief Dr Jason Lewis said that PSMA prostate imaging might "provide benefit to men diagnosed with prostate cancer but in order for this technique to become more widely used in cancer care, access needs to improve".

"Kit-based approaches could prove to be an ideal way to lower cost and make prostate imaging more accessible," Dr Lewis said.

Telix was up 2.5 cents or 3.6 percent to 71.5 cents.

COMPUMEDICS

Compumedics says that due to "unexpected complexities" it expects an outcome to negotiations regarding its joint venture with Health 100 in the next six to 12 weeks.

Earlier this year, Compumedics said it had a framework agreement for a joint venture with China's Meinan Onehealth Healthcare Holdings, or Health 100, which would buy 1,000,000 of its Somfit mobile wearable devices for sleep monitoring over two years after the Somfit device received approval from the China Food and Drug Administration (BD: May 31, 2018).

Compumedics fell 14.5 cents or 24.8 percent to 44 cents with one million shares traded.

COGSTATE

Cogstate says revenue for the 12 months to June 30, 2018 was up 9.6 percent to \$US28,995,680 (\$A39,837,600), with net loss after tax down 12.0 percent to \$US565,918 (\$A777,791).

Cogstate said that its clinical trial business was the main source of revenue up 7.2 percent to \$US28,080,187, with healthcare contributing \$US384,929 and its research and development contracts contributing \$US491,768.

The company said that net tangible asset backing per share was down 14.3 percent at six cents, diluted loss per share was down 16.7 percent to 0.5 US cents, with cash and cash equivalents of \$US4,366,304 at June 30, 2018 compared to \$US7,157,027 for the previous corresponding period.

Cogstate was up 6.5 cents or 12.75 percent to 57.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue for the six months to June 30, 2018 was down 5.8 percent to \$13,490,249, with last year's net profit after tax turned to a \$473,638 loss.

Universal Biosensors said that revenue from products was down \$1.4 million to \$900,000, partly due to Siemens building-up inventory as it began launches of the Xprecia Stride coagulation analyzer test strips,

The company said that revenue from services was \$561,000 and quarterly service fees for sale of test strips was up to \$12,025,000, with Johnson & Johnson subsidiary Lifescan continuing to buy its Onetouch Verio blood glucose strips.

The company said it spent \$11,705,082 for the six months to June 30, 2018, up 32.4 percent compared to the previous corresponding period.

The company said that net tangible asset backing per share was down 22.2 percent to seven cents a share, with diluted earnings per share 0.0 cents compared to the previous period's 1.0 cent diluted earnings per share.

Universal Biosensors said that it held cash and cash equivalents of \$27,902,157 at June 30, 2018, compared to \$26,259,918 at December 31, 2017.

Universal Biosensors was unchanged at 25 cents.

MICRO-X

Micro-X says it expects a potential impairment charge of the carrying value of its investment in Xinray Systems, but did not quantify the amount.

Mixro-X said it expected to publish a quantified impairment charge in its full year results on August 31, 2018.

The company said the potential impairment was due to an agreement between its 30 percent owned Xinray and the Jintan, China-based joint venture Nuray Technology in which Xinray holds 30 percent, as it was unclear if future revenue for Xinray was expected through its investment in Nuray, and whether it would support the current carrying value of Micro-X's investment in Xinray.

Micro-X said the North Carolina-based Xinray provided its carbon nano-tube emitter technology and x-ray tubes.

Micro-X fell three cents or 8.8 percent to 31 cents.

CYNATA THERAPEUTICS

Cynata says investors will vote to approve \$1.8 million in loans for chief executive officer Dr Ross Macdonald and director Dr Stewart Washer, and ratify a placement. Cynata said Dr Macdonald and Dr Washer intended to exercise 2,500,000 options each to with the options exercisable at 40 cent each by September 27, 2018.

The exercise of the options would result in each of Dr Macdonald and Dr Washer acquiring a further 2.5 percent of the company.

The company said in order to exercise the options, it would lend \$900,000 to each director to facilitate the exercise of the options, with Dr Macdonald and Dr Washer to fund \$100,000 of the exercise price.

The company said the loan would have simple (non-compounding) interest rate of 5.20 percent each year for three years, to be paid annually and accrued daily.

Cynata said investors would also vote to issue FIL Investment (Hong Kong) trading as Fidelity International 4,074,320 shares for \$5,194,758, or \$1.275 a share.

The meeting will be held in the Board Room at the offices of the CFO Solution, Level 2, 62 Lygon Street, Carlton South, Victoria on September 12, 2018 at 10am (AEST).

Cynata fell one cent or 0.8 percent to \$1.195.

ADMEDUS

Admedus says it has requested a further extension for its voluntary suspension to “finalize negotiations in relation to a placement”.

Last week, Admedus requested a suspension following its August 2, capital raising trading halt and then an extension until August 13, 2018 (BD: Aug 2, 6, 8, 2018).

Today company requested a further extension until August 20, 2018.

Admedus last traded at 13.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering Technologies says it has requested a trading halt “pending an announcement... in relation to a proposed capital raising”.

Trading will resume on August 15, 2018 or on an earlier announcement.

Visioneering Technologies last traded at 21 cents.

RHYTHM BIOSCIENCES

Merchant Funds Management says it has increased its substantial shareholder in Rhythm from 7,060,000 shares (7.01%) to 8,160,000 shares (8.10%).

The Perth-based Merchant said it bought the 1,100,000 shares on market for \$165,362, or 15.0 cents a share.

Rhythm fell half a cent or 3.45 percent to 14 cents.

IMPEDIMED

Macquarie Group says it has increased its substantial shareholder in Impedimed from 19,466,639 shares (5.13%) to 23,496,932 shares (6.19%).

The Sydney-based Macquarie said it bought and sold shares on market between June 29 and August 8, 2018 for prices ranging between 35 to 46 cents a share.

Impedimed was unchanged at 3.6 cents with 1.2 million shares traded.

[TPI \(TASMANIAN POPPY INDUSTRIES\) ENTERPRIZES](#)

Thorney Opportunities says it has increased its substantial shareholding in TPI from 8,832,604 shares (10.89%) to 9,889,957 shares (12.20%).

The Melbourne-based Thorney said that between May 1 and August 10, 2018 it bought 687,886 shares at “market prices” but failed to provide the cost of the shares as required under the Corporations Act 2001 and acquired 369,467 shares for no payment.

The company said the shares were held by Thorney Opportunities, Thorney Investment Group, Tiga Trading Pty Ltd and Jamahjo Pty Ltd.

TPI was up one cent or 0.8 percent to \$1.30.

[MEDICINES AUSTRALIA](#)

Medicines Australia says it has appointed former Ausbiotech chief executive officer Dr Anna Lavelle as its independent chair, effective immediately.

Medicines Australia said Dr Lavelle joined the board in January 2017 as its first independent director and had acted as deputy chair as well as chair of the recently established independent advisory council.

Former chair of Medicines Australia Wes Cook said that Dr Lavelle had “proven to have a thorough understanding of the bio pharmaceutical and medical technology sectors and has established strong relationships with stakeholders from across the health sector”.

The company said Dr Lavelle was its first woman chair.

[MMJ PHYTOTECH](#)

MMJ says Medipharm Labs has appointed Sybil Taylor as chief marketing officer and Michael Perron as director of business development.

Earlier this year, MMJ said it invested \$C5 million (then \$A5.15 million) for a 6.9 percent shareholding in the privately-owned Barrie, Ontario-based Medipharm, which owned a majority shareholding in the Wonthaggi, Victoria-based Medipharm Labs Australia (BD: Jul 2, 2018).

MMJ fell half a cent or two percent to 25 cents.