



Biotech Daily

Thursday August 23, 2018

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.34 percent on Thursday August 23, 2018 with the ASX200 down 21.6 points to 6,244.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and two were untraded. All three Big Caps rose.

Impedimed was the best for the second day in a row, up a further 10 cents or 28.6 percent to 45 cents with 2.7 million shares traded. Oncosil climbed 11.8 percent; Pro Medicus was up 5.1 percent; Avita and Universal Bio improved more than four percent; Prescient and Telix were up more than three percent; Polynovo and Prana rose more than two percent; with Cyclopharm, Cynata, Nanosonics and Resmed up more than one percent.

Neuren led the falls, down seven cents or 5.5 percent to \$1.195 with 297,177 shares traded. Genetic Signatures and Starpharma lost more than five percent; Ellex fell 4.4 percent; Optiscan and Uscom were down more than three percent; Compumedics and Opthea shed more than two percent; with Actinogen, Bionomics, Clinuvel and Pharmaxis down more than one percent.

BIOTECH DAILY LIBERAL LEADERSHIP EDITORIAL

It is most unusual for Biotech Daily to comment on politics, let alone the internal turmoil of the Liberal Party of Australia.

Today's shut-down of the House of Representatives until September 10, to allow the Liberal Party to sort out its internal squabbling, appears unprecedented in Australia.

When Malcolm Turnbull dispatched former Prime Minister Tony Abbott, there was a continental sigh of relief at the end of bizarre "captains calls" as well as savage cuts to areas he promised would not be cut: health, education, the ABC and SBS.

Prime Minister Turnbull promised to place innovation at the centre of his Government. Instead we had five Innovation Ministers in three years, along with the penny-pinching, counter-productive 1.5 percent cut to the Research and Development Tax Incentive followed by irrational caps on the Incentive, when what was required was independent auditing of applications to weed-out those roting the system.

Today, the Offices of the Health Minister Greg Hunt, Jobs and Innovation Minister Michaelia Cash and Assistant Minister for Science Jobs and Innovation Zed Seselja confirmed that all three had resigned in relation to the Liberal Party leadership turmoil.

The Minister for Small Business Craig Laundy has not resigned.

Yes, we are hugely disappointed that Malcolm Turnbull has not lived up to expectations of being a small "I" Liberal, instead kowtowing to the extreme right-wing of his Party and effectively standing for nothing but his and his Party's survival.

With the Liberal Party ready to remove Mr Turnbull, Labor's Julia Gillard retains the mantle of Australia's second longest serving Prime Minister this Century, after John Howard. Pending tomorrow's Liberal Party meeting Mr Turnbull may miss by a month.

That Liberal Party tacticians chose to go on strike to sort out their own mess and shut down the House of Representatives – the Senate continues to sit at the time of publication – and that Government Ministers have shown such reprehensible disloyalty by resigning in a public humiliation of their leader is outrageous, particularly in that it was driven by those who repeatedly attacked their Labor Opposition for doing precisely the same.

Biotech Daily notes that the single most important legislative change for our sector has been the R&D Tax Incentive, achieved by Ausbiotech on behalf of the sector under the previous Gillard-Greens Government and chipped away by the Abbott-Turnbull Governments.

Liberal Party leadership contenders Peter Dutton and Scott Morrison have shown no interest or empathy for our sector, let alone innovation or the wider Australian community.

The Governor-General should call an election.

David Langsam
Editor

TELEX PHARMACEUTICALS

Telix says it has filed an application for a 250-patient, European, phase III trial of its TLX250 with positron emission tomography imaging for renal, or kidney, cancer.

Telix said the application to the European Medicines Authority proposed a prospective imaging study of kidney cancer patients undergoing kidney surgery to determine the sensitivity and specificity of TLX250 positron emission tomography (PET) imaging to detect clear cell renal cell cancer, compared to observation of cells from tissue samples. The company said the trial of TLX250, or 89-zirconium-desferrioxamine-girentuximab (89-Zr-DFO-girentuximab) would be conducted at more than 15 sites in Europe, the US and Australia pending regulatory approval.

Telix said the study would be referred to as the Zircon study, standing for zirconium imaging in renal cancer oncology.

Telix chief executive officer Dr Christian Behrenbruch said that the European filing “marks a major operational milestone for the company in terms of realizing the value of our product pipeline”.

“In close collaboration with Heidelberg Pharma AG, formerly Wilex AG, Radboud University Medical Centre and Memorial Sloan Kettering [Cancer Centre], Telix has progressed a renal cancer PET imaging program that has the potential to deliver a significant unmet need to a population of cancer patients that are commonly mis-staged”.

“The trial is expected to take nine to 12 months to fully recruit,” Dr Behrenbruch said.

Telix was up 2.5 cents or 3.1 percent to 82 cents.

IMPEDIMED

Impedimed says the first manuscript using data from its 500-patient Prevent trial of its L-Dex device for measuring lymphoedema has been published.

Impedimed said that the study, published in the journal Lymphatic Research and Biology said that L-Dex bio-impedance spectroscopy was used to take measurements of 280 women before breast cancer treatment and at least once within 12 months after treatment. An abstract is available at: <https://www.liebertpub.com/doi/pdf/10.1089/lrb.2017.0070>.

The abstract said were pre-treatment and post-treatment measurements were compared to population norms and maximum L-Dex changes within 12 months.

Impedimed said the study authors recommended “an aggressive measurement protocol consisting of an L-Dex assessment every three months, especially during the first six to 12 months post-surgery to facilitate identification of sub-clinical lymphoedema”

Impedimed chief executive officer Richard Carreon said the publication “significantly adds to our growing body of clinical evidence necessary to obtain payment from private payers”.

Mr Carreon said the publication would be used as part of a submission to the National Comprehensive Cancer Network to establish bio-impedance spectroscopy as the standard-of-care for patients at risk of developing lymphoedema.

Impedimed climbed a further 10 cents or 28.6 percent to 45 cents with 2.7 million shares traded.

GENETIC SIGNATURES

Genetic Signatures says it expects to receive a further \$417,336 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Genetic Signatures said that the Tax Incentive was expected by October 2018 and related to expenditure in the year to June 30, 2017.

Genetic Signatures fell three cents or 5.45 percent to 52 cents.

BIOTECH DAILY EDITORIAL: REPORTING, MATHS AND TAX INCENTIVES

As we head towards the pointy end of reporting season it appears that a large number of companies have accountants and/or auditors who really don't know mathematics, and in some cases, accounting.

The common faults include:

Claiming profit of \$10 is up 200 percent when the previous year was a loss of \$10. No, it's a turnaround. If the \$10 loss was up 200 percent it would be a \$30 loss;

Claiming revenue is up 100 percent to \$2 million means the previous revenue was \$1 million. One company claimed revenue was up 100 percent from no previous revenue;

Changing the previous year's numbers without explanation; and

The most irritating: claiming the Federal Research and Development Tax Incentive as income when it is a tax measure. It is NOT revenue or income, as some companies misleadingly claim on their front page but bury deep in the notes to their 100-plus page reports. It should be in the tax line or reported as a separate item under the tax heading. Biotech Daily would deeply appreciate companies speaking plainly about their revenue, profit and loss, rather than attempting to massage a better result than they have.

David Langsam
Editor

PROBIOTEC

Probiotec says that sales revenue for the year to June 30, 2018 was up 24.9 percent to \$75,725,000 with net profit after tax up 53.6 percent to \$4,276,000.

Probiotec said it would pay a fully-franked 2.0 cents a share dividend for shareholders at the record date of September 5, 2018, following an interim dividend of 0.75 cents a share, compared to a 1.5 cents dividend last year.

The company said that organic sales revenue from contract drug manufacturing, with branded pharmaceuticals generating \$8.0 million in sales, along with revenue from the acquisition of the Sydney-based South Pack Laboratories (BD: Oct 3, 2017).

Probiotec said diluted earnings per share was up 30.0 percent to 6.8 cents and it had cash and cash equivalents of \$1,816,089 at June 30, 2018 compared to \$321,624 at June 30, 2017.

Probiotec was up five cents or 3.1 percent to \$1.64.

CYCLOPHARM

Cyclopharm says revenue for the six months to June 30, 2018, was up 4.7 percent to \$6,341,766, with net less after tax down 52.0 percent to \$684,689.

Cyclopharm said it would pay an unfranked dividend of 0.5 cents a share for investors at the record date of September 10, 2018, the same as the previous year.

The company said that revenue was sales of patient administration sets as well as its Technegas generators for lung imaging for pulmonary embolisms.

Cyclopharm said that net tangible assets per share fell 22.7 percent to 17 cents, compared to 22 cents at June 30, 2017, with diluted loss per share reduced from 2.48 cents at June 30, 2017 to 1.01 cents at June 30, 2018.

The company said that it had cash and cash equivalents of \$7,611,330 at June 30, 2018 compared to \$10,619,920 at June 30, 2017.

Cyclopharm was up one cent or 1.1 percent to 90 cents.

CANN GROUP

Cann says its maiden revenue from customers from the sale of marijuana products for medicinal cannabis for the year to June 30, 2017 was \$616,000.

Cann previously said it was providing medicinal cannabis for the Victoria Government which was conducting a paediatric epilepsy trial, but until now has not posted any revenue (BD: Apr 17, 2017).

The company said its net loss after tax for the year was up 82.6 percent to \$4,725,857 with cash and cash equivalents at June 30, 2018 of \$49,566,890.

Cann fell five cents or 1.8 percent to \$2.74.

THE BURNET INSTITUTE

The Burnet Institute says that Eliminate Hepatitis C Australia “aims to achieve elimination [of the infectious liver disease] by 2030”.

The Burnet said Eliminate Hepatitis C was “Australia’s first nationally coordinated response to hepatitis C” which caused liver cancer and cirrhosis if untreated.

A media release from the Institute said that medications that could cure hepatitis C had been subsidized by the Federal Government until 2021, but more than 170,000 Australians had not sought treatment, or remain unaware they are infected.

The Burnet said the estimated cost to the Australian community of hepatitis C was \$2.4 billion if left untreated.

The media release said that Eliminate Hepatitis C Australia was launched last night at Parliament House in Canberra by the then Federal Health Minister Greg Hunt, in partnership with the Paul Ramsay Foundation.

The Burnet Institute said Eliminate Hepatitis C was “a multi-million dollar targeted, national response to the serious decline in the uptake of highly effective drugs to cure hepatitis C among Australians living with the deadly virus”.

The Institute said that the partnership aimed to eliminate hepatitis C as a public health threat in Australia by 2030, inform government policy, increase hepatitis C awareness, testing and treatment for high risk and vulnerable communities.

The Burnet said the Paul Ramsay Foundation would provide \$11.33 million to Eliminate Hepatitis C Australia to bring together researchers, scientists, government, health services and community organizations to deliver a coordinated national response.

Eliminate Hepatitis C Australia chief investigator and Burnet deputy director Prof Margaret Hellard said it was “critical for Australians infected with hepatitis C to be tested, treated and cured to stop the transmission of new infections and hepatitis C-related deaths”.

The Burnet said that since 2016, 58,000 Australians had begun hepatitis C treatment, including 43,000 in the first 15 months, but the numbers had fallen every month since.

A further 170,000 Australians, particularly Aboriginal and Torres Strait Islanders, injecting drug users, prisoners, and gay and bisexual men, were estimated to have hepatitis C.

MACH 7 TECHNOLOGIES

Mach 7 says Qatar’s Hamad Medical Corporation has upgraded its Mach7 clinical imaging platform to include its Business Continuity Solution product.

Mach 7 said orders from Hamad Medical Corporation and Qatar-based Sidra Medical and Research Centre for technical support of its data service platforms were expected to recognize revenues “of at least \$1.4 million in the current financial year, with a large proportion of this recurring”.

Mach7 was up half a cent or 2.3 percent to 22.5 cents.

[PROTEOMICS INTERNATIONAL LABORATORIES](#)

Proteomics says it has progressed Promarker imaging research for endometriosis, Giardia and lung conditions but has discontinued its mesothelioma research.

Proteomics said a discovery study of Promarker for identifying endometriosis, or the growth of uterine tissue outside the uterus, had found several potential biomarkers in the blood that could be used to test for endometriosis and would now progress to a proof of concept study (BD: Aug 24, 2016).

The company said it was collaborating with Perth's Murdoch University Veterinary School on a proof-of-concept study of Promarker for identifying biomarkers for Giardia for the diagnosis of the giardiasis infection in pets (BD: Oct 20, 2016).

Proteomics said its Giardia test in development was strain specific and could be used to test if pets infected with Giardia presented a risk to their owner.

The company said it had received ethics approval for a discovery study to identify biomarkers for asthma and chronic obstructive pulmonary disease in collaboration with the Busselton, Western Australia-based Busselton Population Medical Research Institute (BPMRI) (BD: Dec 4, 2017).

Proteomics said the collaboration with BPMRI would provide access to the "globally-recognized Busselton Health Study, one of the longest running epidemiological research programs in the world".

The company said was discontinuing its mesothelioma research pipeline after a discovery study in collaboration with the University of Western Australia had found no new biomarkers for proteins associated with asbestos-related cancer mesothelioma (BD: Sep 6, 2016).

Proteomics was up 2.5 cents or 10.6 percent to 26 cents.

[AVITA MEDICAL](#)

Avita says it has begun manufacturing its Recell device at its newly-acquired factory in Ventura, California.

Avita said it acquired the factory on July 1 and that components manufactured in the facility would supply its Recell device for clinical trials, the US launch and international sales (BD: Jun 28, 2018).

Avita was up 0.4 cents or 4.5 percent to 9.3 cents with 3.8 million shares traded.

[USCOM](#)

Uscom says company secretary Brett Crowley will replace Sheena Jack as a non-executive director, effective from today.

Uscom said Mr Crowley was a practicing solicitor and a former partner of Ernst & Young in Hong Kong and Australia, a former partner of KPMG in Hong Kong, had established and managed an unnamed joint venture company in China and was a former senior legal member of the New South Wales Civil and Administrative Tribunal.

The company said Mr Crowley had been its company secretary for the last two years

The company said Ms Jack had resigned after six with the company to focus on her new role as chief executive officer of the not-for-profit health insurance company HCF, formerly the Hospitals Contribution Fund.

Uscom fell half a cent or three percent to 16 cents.

IMUGENE

Imugene says it has appointed Dr Mark Marino as chief medical officer, effective from September 1, 2018.

Imugene said Dr Marino previously held clinical development and chief medical officer positions at the Tokyo, Japan-based Daiichi-Sankyo, the Basel, Switzerland-based Hoffman-La Roche and Sydney's Novartis Pharmaceuticals.

The company said Dr Marino previously led teams in oncology, cardiology, endocrinology and rare-diseases and worked with the US Walter Reed Army Institute of Research.

Imugene said that Dr Marino held Doctor of Medicine from New York's Albert Einstein College of Medicine and a Bachelor of Science in Chemistry from the West Point, New York-based United States Military Academy.

Imugene was unchanged at two cents with eight million shares traded.

RACE ONCOLOGY

Race says Dr John Rothman will retire as chief scientific officer effective from August 31, 2018, with business development consultant Gordon Beck "terminated".

Race said Dr Rothman would continue as a part-time consultant for the company from September 1 to December 31, 2018.

The company said its consulting agreement with Mr Beck had been terminated and a notice of termination had been provided to the Barcelona-based Carthagenetics in relation to their agreement to distribute and sell Bisantrene under its named patient program in Europe (BD: Sep 5; Aug 22, 2016).

Race chief executive officer Peter Molloy said the changes reflected a "strategic refocusing of the company's [named patient program] activities".

Race fell one cent or 7.7 percent to 12 cents.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Dr Gillies O'Bryan-Tear to its scientific advisory board.

Clarity said that Dr O'Bryan-Tear joined the pharmaceutical industry in 1986 and had spent 30 years in clinical development, medical management and commercial roles.

The company said Dr O'Bryan-Tear had worked for pharmaceutical and biotechnology companies in the US and Europe and was involved in multiple product approvals.

Clarity said that in 2009 Dr O'Bryan-Tear was appointed chief medical officer of Norway's Algeta ASA developing a radiopharmaceutical for prostate cancer, which was launched in 2013, with the company acquired in 2014 by Bayer AG for \$US2.9 billion.

The company said that Dr O'Bryan-Tear held a Bachelor of Medicine, Bachelor of Surgery from University College London.

Clarity is a public unlisted company.

SCIGEN

Scigen says it was suspended from ASX quotation at the close of trading on August 22, 2018, following its acquisition by China's Yifan International (BD: May 16, 2018).

Scigen last traded at 6.8 cents.