



# Biotech Daily

Thursday August 2, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH EVEN: GENETIC SIGS UP 15%; ITL DOWN 10%**
- \* **MEDICINES AUSTRALIA ADDRESSES GENDER INEQUALITY**
- \* **LA TROBE UNIVERSITY \$27m MEDICINAL MARIJUANA, OPIUM HUB**
- \* **SIRTEX CDH GENETECH, CHINA GRAND SCHEME MEETING**
- \* **ACRUX FIRST-TO-FILE FOR GENERIC JUBLIA FOR NAIL INFECTION**
- \* **GENETIC SIGNATURES GEN 2 EASYSscreen SALES CONTRACT**
- \* **USCOM LAUNCHES BP+ REPORTER BLOOD PRESSURE INTERFACE**
- \* **POLYNOVO ENROLS US NOVOSORB FEASIBILITY TRIAL**
- \* **RESAPP COMPLETES PAEDIATRIC RESPIRATORY TRIAL ENROLMENT**
- \* **GENETIC TECHNOLOGIES SIGNS BLOCKCHAIN AGREEMENT**
- \* **ADMEDUS REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **ADALTA RELEASES 24.6m ESCROW SHARES**
- \* **CRYOSITE PROFIT WARNING**
- \* **QUEENSLAND BAUXITE CLAIMS MARIJUANA INHIBITS T-CELLS**
- \* **ISRAEL'S SUPERMEDIC TO SELL CRESO CANNAQIX TO MIDDLE EAST**

## MARKET REPORT

The Australian stock market fell 0.55 percent on Thursday August 2, 2018 with the ASX200 down 34.8 points to 6,240.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and four were untraded.

Genetic Signatures was the best, up six cents or 14.6 percent to 47 cents with 87,358 shares traded. Immutep climbed 6.1 percent; LBT improved four percent; Clinuvel and Dimerix were up more than three percent; Benitec, Osprey and Starpharma rose more than two percent; Bionomics, Nanosonics, Polynovo, Resmed and Volpara were up one percent or more; with Sirtex and Telix up by less than one percent.

ITL led the falls, down two cents or 10 percent to 18 cents, with 13,410 shares traded. Impedimed lost 9.3 percent; Compumedics retreated 8.9 percent; Prescient fell 4.35 percent; Actinogen, Mesoblast, Opthea and Pharmaxis were down more than three percent; Medical Developments shed two percent; Avita, Cynata, Neuren, Orthocell and Reva were down more than one percent; with Cochlear, CSL and Pro Medicus down by less than one percent.

## MEDICINES AUSTRALIA

Medicines Australia says women are under-represented as chief executive officers and heads of country, with workplace changes required to approach gender equality.

In a media release, the Medicines Australia Pharma Australia Gender Equity Group said there was a need “for more job flexibility” and noted that pay gaps favored male staff.

The Group said there were three leading ideas from a July 31, 2018 workshop that it would explore “as tactics for promoting gender equity and promoting the brightest talent to the pharmaceutical sector longer term”.

The Medicines Australia Group said it would address: “specific job design for part time work to improve flexibility; improving high potential female talent succession readiness for head of country roles; [and] audits by companies into gender pay gaps, increased transparency around the results and clear action plans to reduce disparities”.

The Group said that the New York-based human resources company Mercer found that the pharmaceutical industry had “strong female representation overall, 60 percent, but this drops to 34 percent at head of organization level.

Prompted by the announcement, Biotech Daily has found that seven of the Biotech Daily Top 40 Index (BDI-40) companies, or 17.5 percent, have women chief executive officers, but of the 130 ASX-listed human health biotechnology companies, there were just 18 women chief executive officers, or 13.85 percent.

Medicines Australia Pharma Australia Gender Equity Group co-chair Kimberly Elliott, an AstraZeneca senior executive, told Biotech Daily that the data was compiled from Medicines Australia 48 member companies.

The Medicines Australia media release said the research showed that women were paid on average 5.2 percent less than male colleagues starting in the same role and there was a seven percent fixed pay gap increase in favor of men when promoted to executive level. Ms Elliott said that “encouraging and promoting gender equity should be a key tactic for attracting the brightest talent into the industry”.

“In many ways we want to go from good to great in the way the industry manages issues like pay equity and equal opportunity,” Ms Elliott said.

“For example, most organizations say they have completed a gender equity pay gap analysis,” Ms Elliott said. “But still one in three companies ... are yet to do that analysis.”

“So, it would be great to see all companies embrace the issue by conducting a gender pay gap audit and then be transparent about the results,” Ms Elliott said.

Ms Elliott said that there were other issues the group would consider longer term, including “supporting men and women to progress their careers around parental leave, strengthening flexible work practices across the sector and engaging men in discussions around gender equity to make sure they do not feel discriminated against”.

“There was a lot enthusiasm around the importance of flexibility and the prospect of jobs which are specifically designed with part-time roles in mind,” Ms Elliott said.

“The point was well made at the workshop today that job sharing for [administration] roles is pretty straight forward,” Ms Elliott said.

“We’ll be exploring what kind of creative job design could be done in the future that would allow a head of country role to be part time or shared,” Ms Elliott said.

“We’ve got good representation of women through the industry so now it’s about trying to ensure that representation is evident across all levels,” Ms Elliott said.

Group co-chair and Johnson & Johnson head of diversity and inclusion Maria Allart, said that “a key question for the industry now is how we support and enable more women to progress to head of organization and senior executive level roles”.

“One key focus in the future will be how we build high potential, succession ready female talent for future head of organization and senior executive opportunities,” Ms Allart said.

## LA TROBE UNIVERSITY, FEDERAL GOVERNMENT CANN GROUP, TPI (TASMANIA POPPY INDUSTRIES) ENTERPRISES

La Trobe University says a more than \$27 million Research Hub for Medicinal Agriculture will be located at its Bundoora, Melbourne campus.

A media release from La Trobe University said the Hub would combine research and industry expertise to create jobs and drive better health outcomes.

La Trobe University said that the Federal Minister for Education and Training Senator Simon Birmingham announced “almost \$5 million ... [for] the La Trobe-led Australian Research Council Industry Transformation Research Hub for Medicinal Agriculture”.

The University said it had committed \$10 million, with \$6 million from industry partners. Senator Birmingham said the Hub was a major step forward for Australia’s developing medicinal agriculture industry.

“This is about injecting knowledge at all parts of the supply chain from producers to manufacturers and exporters to ensure they have the tools to develop and expand their enterprises,” Senator Birmingham said.

La Trobe University vice-chancellor Prof John Dewar said the Hub would position Australia as a world leader and aligned with Victoria’s focus on the emerging medicinal agriculture market.

Prof Dewar said the Hub would “provide a much-needed evidence base around the growth and use of medicinal plants such as cannabis”.

La Trobe deputy vice-chancellor and research head Prof Keith Nugent the University would build “an evidence base around the growth and use of medicinal plants including cannabis and opioids, with the potential to treat a range of chronic medical conditions”.

The University said the resulting value of the Hub was estimated at an additional \$1 billion to \$2 billion a year in potential industry value, resulting in a cumulative benefit of \$5 billion to \$10 billion over the five-year period from 2018 to 2022.

The university said that the Hub comprised agricultural and biomedical researchers with industry partners including Cann Group and TPI Enterprises and research partners including the Olivia Newton-John Cancer Research Institute and the University of Melbourne.

The Hub director Prof Tony Bacic said it would “fill an important gap by conducting vital research into plant varieties, commercial cultivation practices, chemical synthesis and extraction techniques”.

“The Hub will use evidence-based research to safeguard quality, safety, purity, mode of action of cannabinoids and scale of cultivation, and production of medicinal cannabis,” Prof Bacic said. “It will also conduct research on opioids around breeding new, disease-resistant varieties and increasing yield.”

“The Hub will be a powerhouse of research and industry talent in medicinal agriculture, attracting international partners as well as offering \$2 million of scholarships for graduate students, thereby creating a pipeline for new high-skill jobs in the sector,” Prof Bacic said.

“An additional 200 jobs will be generated, benefiting rural and regional Australia via its impact on cultivation and farming practices,” Prof Bacic said.

The University said the Hub would have an industry advisory group chaired by former University of Melbourne vice-chancellor and Cochlear chair Prof David Penington who had been “prominent in guiding the establishment of the policy and regulatory framework within Australia, enabling the establishment of a medicinal cannabis industry in Australia”.

La Trobe University said that the Hub was the first of a number of initiatives from a \$50 million commitment to the La Trobe Institute for Agriculture and Food, which was seeking industry and community partners for new and innovative opportunities to transform the scope, scale and translation of Australian agri-food research and innovation sector.

## SIRTEX MEDICAL

Sirtex says the Federal Court of Australia has approved the despatch of the scheme booklet for CDH Genetech and China Grand Pharmaceutical to acquire the company. In June, Sirtex said it had terminated the \$1.56 billion acquisition by the Paolo Alto, California-based Varian Scheme and had agreed to the \$1.87 billion binding scheme deed with China's CDH Genetech and China Grand Pharmaceuticals (BD: Jun 15, 2018). The company said its board unanimously recommended that shareholders vote for the scheme, in the absence of a superior proposal and subject to the independent experts continuing to conclude that the scheme was in the best interests of shareholders. Sirtex said it expected to implement the scheme on September 20, 2018 and the scheme meeting would be held at the Royal Automobile Club of Australia, 89 Macquarie Street, Sydney on Monday, 10 September 2018 at 10am. Sirtex was up five cents or 0.2 percent to \$31.90 with 454,735 shares traded.

## ACRUX

Acrux says it has submitted a first-to-file application to the US Food and Drug Administration for generic Jublia for the fungal nail infection onychomycosis. Acrux said the abbreviated new drug application (ANDA) had been accepted by the FDA and would give it 180 days of generic exclusivity for generic Jublia, or efinaconazole, for fungal infection of the nail bed in toes and fingers. The company said the ANDA contained data that demonstrated that its generic product was bioequivalent to Jublia. Acrux said that after FDA approval and any litigation, it would be able to sell generic Jublia in the US, where Jublia had more than \$280 million a year. Earlier this year, in a teleconference on its half-year results, Acrux chief executive officer Michael Kotsanis said the company had dropped its lead ACR-065 for onychomycosis program and that it had previously been announced in a slide in the annual general meeting presentation on October 26, 2017 (BD: Feb 21, 2018). Today, Mr Kotsanis said the company was "pleased that the first product in our current pipeline of 13 generic topical products is now being reviewed by the FDA for approval". "This first-to-file ... [application] is the first example of our investment in our topical generic strategy and is the result of the great work by our R&D team," Mr Kotsanis said. Acrux was up 2.5 cents or 16.1 percent to 18 cents with 2.7 million shares traded.

## GENETIC SIGNATURES

Genetic Signatures says a contract with an unnamed pathology laboratory could see up to 1,000 tests a day for its second generation Easyscreen respiratory diagnostic kit. Genetic Signatures said the sales agreement with the Australian laboratory for the Easyscreen respiratory pathogen detection kit and GS1-HT laboratory instrumentation could involve the supply of "up to 1,000 tests per day during peak 'flu season and approximately 100 to 200 outside of the 'flu season". The company said the agreement coincided with the release of its second generation Easyscreen respiratory pathogen detection kit and its GS1-HT sample processing and amplification laboratory equipment. Genetic Signatures said that Easyscreen was currently for "research use only" and that it expected to receive regulatory registration from the Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark approval in the coming months. Genetic Signatures was up six cents or 14.6 percent to 47 cents.

## USCOM

Uscom says it has released the BP+ Reporter computer interface for its BP+ supra-systolic oscillometric blood pressure monitor.

Uscom said the BP+ Reporter provided new patient archiving, image storage, analysis, parametric trending and reporting of blood pressure data.

The company said its BP+ and BP+ Reporter measured and stored more than “25 parameters of cardiovascular function and three pulse pressure waveforms from the heart, aorta and the arm from each 45 second measure”.

Uscom chief executive officer Prof Rob Phillips said the hypertension was “common, dangerous, expensive and poorly managed, with new studies suggesting central [blood pressure], as measured by the BP+, significantly improves diagnosis and management of BP and is expected to improve patient compliance”.

“The BP+ Reporter puts the “plus” into blood pressure monitoring and hypertension management and changes the way we look at the disease,” Prof Phillips said.

Uscom was untraded at 16.5 cents.

## POLYNOVO

Polynovo says it has completed enrolment of its 15-patient US-based feasibility trial of its Novosorb wound treatment.

Polynovo said it would follow the patients for 12 months after the closure of their wounds and, in conjunction with the monitoring of patients, would build the protocol and dossiers required for an US Food and Drug Administration-approved pivotal trial.

The company said recruitment of the last patient was “a significant milestone in the progression towards a full thickness burn regulatory claim via pre-market approval with the US FDA”.

Polynovo was up half a cent or one percent to 51 cents.

## RESAPP HEALTH

Resapp says it has completed enrolment of 681 patients in its paediatric, Perth-based study of its smartphone diagnostic for acute respiratory disease.

Resapp said the study would evaluate its Resappdx software application in diagnosing acute childhood respiratory diseases, with top-line results expected later this month.

Yesterday, Resapp said it had completed enrolment for its 1,470 patient Smartcough-C-2 respiratory disease diagnostic study at three US hospitals (BD: Aug 1, 2018).

Resapp fell half a cent or three percent to 16 cents with 5.3 million shares traded.

## GENETIC TECHNOLOGIES

Genetic Technologies says it has a framework agreement with Blockchain Global to combine genetic screening with blockchain technology.

Genetic Technologies said the agreement formalized a non-binding agreement for an alliance with Melbourne’s Blockchain for its digital technology to provide efficiencies and opportunities leveraging its existing genomics business (BD: Feb 5, 2018).

The company said the agreement, pending shareholder approval, would involve the issue of 486,000,000 Genetic Technologies shares to Blockchain in three tranches subject to the achievement of certain milestones.

Genetic Technologies was unchanged at 1.1 cents with 5.3 million shares traded.

## ADMEDUS

Admedus has requested a trading halt “pending an announcement regarding a capital raising”.

Trading will resume on August 6, 2018 or on an earlier announcement.

On Tuesday, Admedus said in its Appendix 4C quarterly report that it had cash and cash equivalents of \$4,426,000 at June 30, 2018 and \$5,000,000 in a loan facility, with an estimated cash outflow for the next three months of \$12,573,000 and customer receipts for the six months to June 30 of \$14,374,000 (BD: Jul 31, 2018).

Last year, Admedus said the San Francisco-based Partners for Growth provided “a secured debt facility” up to \$10,000,000 consisting of a \$5,000,000 “revolving line-of-credit” at an interest rate of 9.75 percent and a \$5,000,000 term loan at an interest rate of 11.75 percent repayable in 36 months, along a seven-year warrant, or option, for the issue of 4,938,799 shares exercisable at 25 cents a share (BD: Oct 26, 2017).

Earlier this year the company said it raised \$6m in a share placement in May and \$2,761,072 in a share-plan in June (BD: May 10; Jun 4, 2018).

Admedus last traded at 13 cents.

## ADALTA

Adalta says that 24,635,549 shares will be released from ASX escrow on August 22, 2018.

According to Adalta’s most recent Appendix 3B new share issue announcement, following the release of the shares, it would have 115,490,062 shares available for trading.

Adalta was up 1.5 cents or 5.1 percent to 31 cents.

## CRYOSITE

Cryosite says it expects loss after tax for the year ending June 30, 2018 to be between \$1.2 million and \$1.3 million.

Cryosite said the loss was principally due to the write-downs and one-off expenses in the first half of the year relating to the closure of the collection and processing of cord blood and tissue component of its business.

The company said it expected to incur “substantial legal costs” in the 2018-'19 financial year due to the Australian Competition and Consumer Commission proceedings relating to the proposed licence and sale of cord blood banking and tissue assets to Cell Care Australia (BD: Jul 12, 2018).

“Clearly 2019 will be a challenging year ... [but] the company expects to end the year with a clear focus and a profitable and growing clinical trial logistic business supported by the long-term storage of cord blood and tissue,” Cryosite said.

The company said it expected a “small before tax profit from continuing operations in the second half of the year” and that a positive cashflow from operations for the full year was offset by an investment in infrastructure resulting in a net \$4000,000 outflow.

The company said that from July 1, 2018 it would adopt the accounting standard AASB15, which would affect how it accounted for its long-term cord blood and tissue contracts.

Cryosite said revenue and costs for the processing and collection would be counted over the life of the contract as opposed to the previous standard where they were taken into account when processing and collection was carried out, resulting in its net assets being reported as \$100,000 after July 1, as opposed to negative \$100,000 before the change.

Cryosite was up 0.4 cents or 6.7 percent to 6.4 cents.

### QUEENSLAND BAUXITE

Queensland Bauxite says sponsored research with Medical Cannabis claims that cannabinoids from a specific cannabis strain inhibits T-cell proliferation  
Queensland Bauxite said a study by the Haifa, Israel-based Technion Institute used an in-vitro system of mononuclear differentiated dendritic cells to mimic multiple sclerosis and found cannabinoids with the capacity to inhibit dendritic-dependent T-cell proliferation  
The company said trials in mice would commence this week.  
Queensland Bauxite was in a suspension and last traded at 3.7 cents.

### CRESO PHARMA

Creso says it has signed an agreement with the Haifa, Israel-based Supermedic to sell its Cannaqix marijuana food supplement in Israel and unnamed Middle East countries.  
Creso said that Supermedic would sell a first line of products based on hemp-seed oil to meet Israeli regulations and then switch to the original Cannaqix formulation when Israeli cannabidiol regulations change.  
The company said that product would be sold under Creso's Cannaqix brand with the option for Supermedic and its customers to co-brand.  
Creso fell half a cent or 0.8 percent to 63 cents.