



# Biotech Daily

Monday October 9, 2017

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: DIMERIX UP 14%; BENITEC DOWN 9%**
- \* **AUSBIOTECH INVEST, CONFERENCE A FORTNIGHT TO GO**
- \* **LBT RECEIVES \$4m FEDERAL R&D TAX INCENTIVE**
- \* **RESMED CLAIMS SLEEP MASK PATENT WINS OVER FISHER & PAYKEL**
- \* **MORE DATA BACKS AIRXPANDERS AEROFORM BREAST EXPANDER**
- \* **USCOM: 'STUDY BACKS MONITOR FOR ICU FLUIDS'**
- \* **BOTANIX, FDA PRE-IND CANNABIDIOL BTX1503 FOR ACNE MEETING**
- \* **MEDIBIO, OTSUKA WORK ON HEART TEST FOR MENTAL ILLNESS**
- \* **CYNATA HIRES FINANTEC TO RAISE JAPAN PROFILE**
- \* **STARPHARMA, PETER MAC WIN \$50k FEDERAL DEP ONCOLOGY GRANT**
- \* **AVITA REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **ASX LIFTS ANTEO SUSPENSION ON ACCOUNTS**
- \* **NUHEARA JUSTIN MILLER, WASAGI, DAVID CANNINGTON DILUTED TO 8%**
- \* **ADALTA APPOINTS DR DALLAS HARTMAN COO**

## MARKET REPORT

The Australian stock market climbed 0.5 percent on Monday October 9, 2017 with the ASX200 up 28.6 points to 5,739.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and three were untraded.

Dimerix was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 600,000 shares traded. Uscom climbed 9.4 percent; LBT and Prana were up more than five percent; Factor Therapeutics improved 4.4 percent; Psivida was up 3.85 percent; Acrux, Medical Developments, Opthea, Starpharma and Volpara rose more than two percent; with Bionomics, Cochlear, Compumedics, CSL and Pro Medicus up by more than one percent.

Benitec led the falls for the second trading day in a row, down 1.5 cents or 9.1 percent to 15 cents with 348,062 shares traded. Universal Biosensors lost 6.1 percent; Oncosil fell 4.2 percent; Ellex and Orthocell were down more than three percent; both Impedimed and ITL shed 2.4 percent; Actinogen, Mesoblast, Neuren, Osprey and Polynovo were down more than one percent; with Airxpanders, Resmed, Sirtex and Viralytics down by less than one percent.

## AUSBIOTECH

Ausbiotech says it will hold its Biotech Invest meetings in Melbourne on October 24, followed by its annual conference in Adelaide, from October 25 to 27, 2017.

Ausbiotech said the annual Biotech Invest 'Connecting Capital with Innovation' event would be held at Melbourne's Sofitel Hotel with Australian life science companies presenting to an expected 200 investors.

The industry organization said an exhibition area would enable companies to present their business case and technologies and engage directly with prospective partners.

For more information, go to: <http://ausbiotechinvestment.com.au/>.

Ausbiotech said it expected 1,000 delegates to attend the Adelaide conference October 25 to 27 and hear presentations from about 90 speakers, with a "focus on the achievements and future of the life sciences sector, linking business, science and government with research, to address the challenges and opportunities facing industry".

The organization said the conference would "attract the entire biotechnology ecosystem" to share ideas and advance the sector's development, allowing companies to showcase technological innovation, knowledge and business networking, offering opportunities to share information with leaders from across the industry spectrum and with pharmaceutical companies interested in partnering and investing in Australia's pipeline of biotechnologies and assessing potential business deals.

Ausbiotech chief executive officer Glenn Cross said the "Australian life sciences industry has a great story to tell and Ausbiotech 2017 will showcase the industry's progress, while providing space to connect, collaborate and meet with ... potential partners".

The organization said that deputy chief executive officer Lorraine Chiroiu would chair a discussion on 'Key issues facing big pharma globally' with a panel of representatives from pharmaceutical companies including Merck Research Laboratories head of business development Benjamin Thorner, Abbvie head of search and evaluation Dr Kevin Lynch, Pfizer head of external science and innovation Dr Anand Gautam, Amgen business development executive director Jessica Droge Johnson & Johnson Innovation Australia and New Zealand new ventures director Kathy Connell and Novartis strategic partnerships head Marie Lindner.

Ausbiotech said that the Prof Nancy Millis Orator would be Biocurate's Dr Glenn Begley, with other speakers including Pfizer's Barbara Sosnowski, Mesoblast's Prof Silviu Itescu, Cell Therapies Dr Tim Oldham, Race Oncology's Peter Molloy and Certara head of D3 Medicine Dr Craig Rayner.

The organization said that the Federal Government's Office of Innovation and Science Australia chief executive officer Dr Charlie Day would provide an update on the Innovation Science and Research system review and its 2030 strategic plan.

Ausbiotech said that as well as presenting the program of speakers, it would facilitate meetings between participants from biotechnology, biopharmaceuticals, life sciences, business, investment, research and health.

For more information and to register, go to: <http://www.ausbiotechnc.org/>.

## LBT INNOVATIONS

LBT says it has received \$4,198,256 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

LBT said that \$3,981,845 of the payment related to research and development expenditure in Australia and overseas for the year to June 30, 2017, with a further \$216,411 relating to an amended claim for the year to June 30, 2015.

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

## RESMED

Resmed says a German court has concluded that Fisher & Paykel's Simplus, Eson and Eson 2 sleep apnoea and snoring masks infringe two of its European patents.

Resmed said that it was involved in patent infringement litigation with Fisher & Paykel.

The company said that the court stayed the infringement proceedings to permit Resmed to defend the validity of its patents in the European Patent Office.

Resmed said in the UK it was proceeding to trial in defence of one of three UK patents that Fisher & Paykel challenged, while agreeing to revoke the other two UK patents.

The company said the UK litigation did not involve any allegations against any of its own products, would have no commercial impact on sales of its products, and was not binding on the European Patent Office or the German courts.

Resmed said that in Australia, after it presented its evidence defending a key mask patent, Fisher & Paykel withdrew its challenge and must pay Resmed's court costs.

Resmed general counsel and chief administrative officer David Pendarvis said the company would "continue to stand against those we believe have unlawfully violated our patents".

"We have more than 5,000 patents in our portfolio, reflecting three decades and millions of dollars of sustained investment in research and development, focused on ensuring that patients around the world receive the high-quality care they deserve," Mr Pendarvis said.

"We're confident, as we've seen in these early rulings, that Resmed will ultimately prevail against Fisher & Paykel," Mr Pendarvis said.

Resmed fell one cent or 0.1 percent to \$9.91 with 894,867 shares traded.

## AIRXPANDERS

Airxpanders says all 50 women in a study of its Aeroform breast tissue expander system report successful expansion and exchange to breast implants.

Airxpanders said the Xpand II trial data was presented at the American Society of Plastic Surgery meeting in Orlando, Florida, October 6 to 10, 2017 by the New York-based Columbia University's Dr Jeffrey Ascherman.

The company said that the primary endpoint of achieving successful expansion and exchange to breast implant, precluding non-device related failures, was met by all patients, with women achieving tissue expansion in a median time of 21 days and completing the reconstruction process in a median time of 115 days.

Airxpanders said surgeons and patients reported high satisfaction rates of 96 percent, with ease of use reported as 98 percent for patients and 94 percent for physicians, and convenience rated at 100 percent for patients and 94 percent for physicians.

Airxpanders chief executive officer Scott Dodson said the Xpand II trial "reaffirms the consistent, outstanding performance and patient benefits of the Aeroform system we've seen across all of our clinical trials and in commercial use".

"With our full US launch underway, we are pleased to be able to provide plastic surgeons access to the most studied, peer reviewed and published tissue expander on the market today," Mr Dodson said.

Airxpanders said that Miami Shores, Florida radiation oncologist Dr Martin Keisch presented on treating patients with radiation therapy with Aeroform in-situ.

The company said that data from 10 Aeroform patients in Perth, Western Australia showed that "by considering specific radiation planning techniques related to the components of the expander, the radiation oncology team could safely deliver radiotherapy with an Aeroform expander in place ... [with] no increase in acute toxicity".

Airxpanders fell half a cent or 0.7 percent to 73 cents.

## USCOM

Uscom says a study has shown “excellent correlation and agreement” between its monitor and echocardiography, the gold standard for measurement of heart function.

Uscom said the Uscom 1A ultra-sonic cardiac output monitor identified the need for fluid with 95 percent sensitivity and specificity in the 121-patient, prospective trial.

The company said fluid was the most common critical care and peri-operative intervention in critically ill neonates, children and adults, with more than 50 percent of all fluids currently used being unnecessary or harmful and fluid management a challenge in medicine, with particular relevance in paediatrics, anaesthesia, critical care and sepsis.

Uscom said its monitor was “a cost effective solution” and the study found the Uscom 1A resulted in 95 percent of patients receiving appropriate fluid, suggesting improved care, significant cost savings and reduced hospital stay, while previously invasive blood pressure monitoring devices failed in free-breathing patients, those with cardiac dysrhythmias, and those with serious diseases such as sepsis and the Uscom device showed high levels of effectiveness even in most difficult intensive care unit patients.

The study, entitled ‘Comparison of continuous-wave Doppler ultrasound monitor and echocardiography to assess cardiac output in intensive care patients’ was published in the journal Critical Care and Resuscitation, with an abstract available at:

<https://www.ncbi.nlm.nih.gov/pubmed/28866972>.

The company said that echocardiography was considered accurate, but the American Society of Echocardiography did not recommend its use as a monitor as it was complex to implement, time-consuming, required years of training and accreditation, and its use was not supported by evidence.

Uscom said its monitor required two days training, was simple to implement with less than five minutes per examination, was relatively inexpensive and had proof of efficacy.

Uscom executive chairman Prof Rob Phillips said the data was “the kind of evidence we need to support widespread adoption in cost stressed global health systems”.

“Not only is Uscom 1A equivalent to the current gold standard but it increases the accuracy of identifying fluid responsiveness from 50 percent to 95 percent and is applicable in the most complex of ICU patients,” Prof Phillips said.

“This evidence demonstrates that patients examined using Uscom 1A receive improved and cost-effective cardiovascular care,” Prof Phillips said.

Uscom was up 1.5 cents or 9.4 percent to 17.5 cents.

## BOTANIX PHARMACEUTICALS

Botanix says it has had a “pre-investigational new drug meeting” with the US Food and Drug Administration for phase II trials of the topical cannabidiol BTX1503 for acne.

Botanix said the meeting provided an opportunity for clarification from the FDA on the development plan and data package required for US phase II studies to start by July 2018, and “enabled Botanix to gain confirmation from the FDA on the overall drug development plan required for BTX1503 “to support a new drug application”.

Botanix executive director Matt Callahan said that following the “pre-IND meeting ... [the company had] a clear and rapid path to commence the phase II study program in the US following completion of our phase Ib study”.

The company said it previously submitted a regulatory package detailing the phase II study, together with the scientific rationale and details of the safety data.

Botanix said it was conducting a 20-patient, phase Ib acne patient study in Australia expected to be completed by the end of December 2017.

Botanix was unchanged at 4.6 cents with 2.98 million shares traded.

## MEDIBIO

Medibio says it will work with the Tokyo, Japan-based Otsuka Pharmaceutical to clarify the role of biomarker-based measures in management of mental illness.

Medibio said it would apply its cardiac rhythm test for depression and other psychiatric illnesses to Otsuka clinical data to characterize circadian, autonomic and sleep biomarkers related to mental illness.

The company said it would be paid for services provided.

Medibio chief executive officer Jack Cosentino said the company was “excited about working with Otsuka, a recognized worldwide leader in treatments for serious mental illness, to advance our mutual understanding of the biology that underpins mental illness, with the goal of improving outcomes”.

Medibio did not provide any further information about the development and commercialization agreement.

Medibio fell two cents or five percent to 38 cents with 1.8 million shares traded.

## CYNATA THERAPEUTICS

Cynata says it has hired the Tokyo-based investor relations firm Finantec Co to raise its profile with Japan’s investment community.

Cynata said that Finantec had connections to high net worth and institutional investors in Japan and the appointment marked “a new phase in Cynata’s global exposure to sophisticated investors with an interest in emerging stem cell and regenerative medicine companies”.

The company said that Finantec would develop and manage investor communication programs in Japan.

Cynata said its strategic partnership with Fujifilm had resulted in a “strong profile in the Japanese media”.

Cynata chief executive officer Dr Ross Macdonald said Japanese economy was “the third largest in the world and is on its longest growth streak in more than a decade, so the time is right for us to increase our awareness among local Japanese investors”.

The company said it would present at the ‘Emerging Technologies and Products in Regenerative Medicine’ session at Bio-Japan 2017 being held in Yokohama, October 11 to 13, 2017.

Cynata was up 1.5 cents or 2.3 percent to 66 cents.

## STARPHARMA

Starpharma says with the Peter MacCallum Cancer Centre it has won a \$50,000 Federal Government Innovation Connections grant for its oncology program.

Starpharma said its dendrimer-enhanced product (DEP) platform improved efficacy and reduced off-target toxicity to improve therapeutic outcomes for cancer patients.

The company said that oncology drugs were commonly used in combination to achieve optimal impact on cancer cells and the funding would be used to assess new and existing DEP candidates in combination with existing therapeutic agents.

Starpharma chief executive officer Dr Jackie Fairley said the work with the Peter MacCallum Cancer Centre “could generate important data aimed at improving treatment regimens and further enhances commercialisation opportunities for Starpharma’s DEP technology”.

Starpharma was up 3.5 cents or 2.55 percent to \$1.41 with 760,196 shares traded.

### AVITA MEDICAL

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

Trading will resume on October 11, 2017 or on an earlier announcement.

Avita last traded at 8.5 cents.

### ANTEO DIAGNOSTICS

The ASX says Anteo’s suspension would be lifted prior to the start of trading today, October 9, 2017 following lodgement of its annual report for the year to June 30, 2017. Anteo fell 0.4 cents or 28.6 percent to one cent with 17.5 million shares traded.

### NUHEARA

In separate announcements, David Cannington and Wasagi Corp say their 63,142,857 share holdings in Nuheara have been diluted from 11.0 percent to 7.91 percent.

Both Mr Cannington and Wasagi said that dilution was caused by the July \$9.0 million placement at 9.2 cents share (BD: Jul 20, 2017).

The Mount Lawley, Western Australia-based Wasagi notice was signed by director Justin Miller.

Mr Cannington said his address was Fairfax, California.

Nuheara executive chairman Justin Miller told Biotech Daily that Wasagi was his private company and the shareholdings belonged to the co-founders, explaining the equal number of shares.

Nuheara fell 0.1 cents or 1.7 percent to 5.7 cents with 5.7 million shares traded.

### ADALTA

Adalta says it has appointed Dr Dallas Hartman as its chief operating officer, effective from today, October 9, 2017.

Adalta said that Dr Hartman had experience in preclinical development and manufacturing for scale-up and previously was Nexvet Biopharma head of product development for 20 years.

The company said that prior to that role, Dr Hartman was CSL’s director of analytical biochemistry.

Adalta was untraded at 22.5 cents.