



Biotech Daily

Wednesday October 28, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: POLYNOVO UP 9%; AMPLIA DOWN 15%**
- * **BIOCURATE, ABBVIE ACCELERATE DRUG COMMERCIALIZATION**
- * **EMVISION PILOT STROKE STUDY MEETS PRIMARY ENDPOINT**
- * **CLINUVEL PILOT PHASE IIa SCENESSE FOR STROKE STUDY**
- * **TELIX, DKFZ PROSTATE SURGERY IMAGING LICENCE**
- * **VOLPARA H1 RECEIPTS UP 33.2% TO \$9.1m 'DESPITE COVID-19'**
- * **MTP CONNECT \$300k FOR AUSBIOTECH REGENERATIVE MEDICINE BODY**
- * **TAIWAN APPROVES POLYNOVO NOVOSORB BTM FOR BURNS**
- * **PAINCHEK EXTENDS ALAYACARE LICENCE TO CANADA**
- * **RESAPP LAUNCHES RESAPDX ON SAMSUNG DEVICES**
- * **PERENNIAL TAKES 13.5% OF GENETIC SIGNATURES**
- * **DR JOHN MCBAIN, PICTON, 52nd CELEBRATION TAKE 15% OF RHINOMED**
- * **IMPEDIMED AGM 16% OPPOSE 10% CAPACITY**
- * **RACE 5.6m DIRECTORS OPTIONS AGM**
- * **AUSCANN HIRES KIDDER WILLIAMS; ADVISORS; SUSPENDS FACILITY**
- * **HYDRIX REQUESTS CAPITAL RAISING TRADING HALT**
- * **AUSBIOTECH APPOINTS LINDA PETERSON DIRECTOR**
- * **RACE LOSES DIRECTORS DR BILL GARNER, CHRIS NTOUMENOPOULOS**

MARKET REPORT

The Australian stock market was up 0.11 percent on Wednesday October 28, 2020, with the ASX200 up 6.7 points to 6,057.7 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 15 fell and three traded unchanged.

Polynovo was the best, up 22 cents or 8.7 percent to \$2.74, with 6.6 million shares traded. Actinogen and Osprey climbed more than four percent; Prescient and Resmed improved more than three percent; Compumedics, Immutep, Impedimed, Medical Developments and Mesoblast rose two percent or more; Clinuvel, Cyclopharm, Genetic Signatures, Imugene, Neuren, Pro Medicus, Telix, Universal Biosensors and Volpara were up more than one percent; with CSL, Kazia, Nanosonics, Next Science and Paradigm up by less than one percent.

Amplia led the falls for the second day in a row, down 3.5 cents or 15.2 percent to 19.5 cents, with 2.1 million shares traded. Alterity and Uscom lost more than eight percent; Cynata retreated 6.9 percent; Dimerix shed 5.4 percent; Antisense, Pharmaxis and Proteomics fell more than four percent; Oncosil was down 3.7 percent; Opthea shed 2.2 percent; with Avita, Nova Eye, Optiscan and Orthocell down by more than one percent.

BIOCURATE

Biocurate says it has a memorandum of understanding with the Chicago-based Abbvie “to bring new medicines to patients faster”.

Biocurate, a University of Melbourne and Monash University joint venture, said it aimed to translated medical research to therapies, while Abbvie collaborated with hundreds of biotechnology companies, universities, not-for-profits and government organizations. The organization said it had several projects from the two Universities under management in its investment portfolio and under the agreement the companies might collaborate on projects of specific interest within the portfolio.

Biocurate said that Abbvie would provide scientific advice and commercial perspective for projects within their therapeutic areas of focus including immunology, oncology, gastroenterology, virology, neuroscience, eyecare, women’s health and aesthetics.

Biocurate chief executive officer Dr Glenn Begley said the partnership was “testament to the high calibre of Australian research”.

Abbvie Australia and New Zealand general manager Chris Stemple said Australia had “a long-standing reputation as a world leader in medical research, but unfortunately also one for being below average in commercialization.”

“At Abbvie, we bring people together because we know that collaboration is the key to breaking barriers and exploring new frontiers in science,” Mr Stemple said.

“This collaboration with Biocurate is an exciting example of a partnership that aims to increase the speed at which new treatments are made available to those who need them,” Mr Stemple said.

EMVISION MEDICAL DEVICES

Emvision says a pilot trial of 30 ischaemic and haemorrhagic stroke patients has met its primary endpoint to collect a dataset of patients to advance its imaging algorithm.

Emvision said the study, conducted at Brisbane’s Princess Alexandra Hospital, aimed to differentiate between 21 ischaemic stroke patients and nine haemorrhagic stroke patients. The company said its imaging technology was able to differentiate between haemorrhagic and ischemic stroke with a 93.3 percent accuracy rate, was able to localize the correct quadrant with an 86.7 percent accuracy and the scans were well-tolerated.

Emvision said the datasets, which included five datasets where pathologies had been estimated to fall outside the hardware range, had advanced its imaging and classification algorithm development and it observed a correlation between its scans and computed tomography (CT) and magnetic resonance imaging (MRI) scans.

The company said the datasets did not enable statistically significant conclusions, but did allow it to advance the hybrid fusion methodology to extract the target lesion and estimated location in each algorithm and apply a pixel-wise voting algorithm.

Australian Stoke Alliance co-chair and past president of the World Stroke Organisation Prof Stephen Davis said the data was “highly encouraging, clearly showing localization of ischaemic and haemorrhagic events [and] an important future step will be testing the fusion approach for specificity and sensitivity to blood”.

Emvision chief executive officer Dr Ron Weinberger said the “promising results, the first in stroke patients for our technology, provide a strong foundation with which to progress our development program”.

“These results ... indicate that we are able to discriminate and localize haemorrhagic and ischaemic strokes with an encouraging degree of accuracy under these conditions.” Dr Weinberger said.

Emvision was up six cents or 2.1 percent to \$2.90 with 473,374 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says a pilot phase IIa study of six arterial ischaemic stroke patients will assess the safety and effectiveness of its Scenesse or afamelanotide.

Clinuvel said the six-week study at a single expert neurological emergency centre would assess brain injury and neurological functions through magnetic resonance imaging.

The company said the primary objective would be safety and the secondary objective would be to assess whether the therapy affected the size of salvageable ischaemic brain tissue by increasing blood flow, restoring oxygen supply and reducing fluid formation.

Clinuvel said ischaemic strokes accounted for 85 percent of the 15 million global stroke cases each year and the current standard therapy relied on early intervention to restore blood flow by either chemically dissolving or physically removing the blood clot.

Clinuvel chief scientific officer Dr Dennis Wright said that “for years we had prepared for the use of afamelanotide in stroke patients, given the broad effectiveness of the hormone and the significant medical need to improve clinical outcomes in these patients”.

The company said it would begin recruitment once Covid-19 restrictions on medical staff had eased, with results expected by July 2021.

Clinuvel was up 26 cents or 1.2 percent to \$21.87 with 204,104 shares traded.

TELIX PHARMACEUTICALS

Telix says it has an exclusive agreement with the German Cancer Research Center to licence its fluorescent imaging agent for prostate cancer surgery.

Last year, Telix said it would collaborate with the Deutsches Krebsforschungszentrum (German Cancer Research Centre or DKFZ) for an imaging agent that combined its TLX591-CDx with a fluorescent dye to guide surgery and included “a fully negotiated exclusive option to licence the technology from DKFZ” (BD: Aug 5, 2019).

Today, the company said the imaging agent provided both pre-operative imaging through positron emission tomography (PET) scans and “highly accurate intra-operative visual fluorescent localization of prostate cancer tissue in real-time”.

Telix said it would pay development milestones and royalties on product sales for the technology, which included a prostate-specific membrane antigen (PSMA)-targeting molecule comprising the radioactive isotope Gallium-68 and a fluorescent dye.

Telix chief executive officer Dr Chris Behrenbruch said that robotic surgery delivered more than seven million procedures a year, with “extensive use of ... fluorescent imaging”.

“Bringing molecular imaging into the operating theatre is a natural evolution of Telix’s existing commitment to prostate cancer imaging,” Dr Behrenbruch said.

The company said it expected to start sponsored clinical studies by December 31, 2021.

Telix was up two cents or 1.2 percent to \$1.665.

VOLPARA HEALTH TECHNOLOGIES

Volpara says receipts from customers for the six months to September 30, 2020 were up 33.2 percent to \$NZ9,644,000 (\$A9,066,445) despite Covid-19 restrictions.

Volpara said receipts for its breast mammography software and services for the three months to September 30, 2020 were down 5.6 percent to \$NZ4,682,000 and it had \$NZ64,293,000 million in cash on hand at September 30, 2020.

Volpara chief executive officer Dr Ralph Highnam said, “we see little material changes in our overall cash receipts due to Covid-19, which shows the resilience of our industry and business model”.

Volpara was up 1.5 cents or 1.1 percent to \$1.415.

[MTP CONNECT, AUSBIOTECH](#)

MTP Connect says it has awarded \$300,000 to an Ausbiotech-led consortium for a collaboration and coordination body for Australian regenerative medicine.

MTP said the funding was from its Federal Government initiative Industry Growth Centre Project Fund and would be matched by the seven collaboration body partners, including Biointelect, Cell Therapies, Medicines Australia, MTP Connect, Novartis Pharmaceuticals Australia and Research Strategies Australia.

In a joint media release, Ausbiotech said the 12-month project would include the development of a roadmap for regenerative medicine development in Australia, determination of a sustainable funding and model structure and development of a regulatory white paper.

The organization said the project also aimed to establish annual data points and information resources, to map a pathway for a typical product to market and to map a pipeline of future gene and cell therapies.

Ausbiotech said that the body would address priority action areas, including workforce capabilities, collaboration, funding, regulation, policy infrastructure and manufacturing capability.

MTP Connect said regenerative medicine harnessed the body's regenerative capabilities with new technologies, included nanotechnology, bioengineering and stem cell therapies, and could be worth \$6 billion in annual revenue and 6,000 jobs for Australia by 2035 if successful.

The organization said there were currently more than 30 companies developing regenerative medicine products in Australia, with more than 30 clinical trials in progress.

[POLYNOVO](#)

Polynovo says the Taiwan Food and Drug Administration has approved its Novosorb biodegradable temporizing matrix (BTM) for burns injuries.

Polynovo said it had contracted Evermed to sell Novosorb, which would begin after lodging reimbursement data with the health authority, which was typically a three-month process.

The company said it expected first sales in March 2021.

Polynovo managing director Paul Brennan said Taiwan had "an advanced health system and has a population of circa 23 million concentrated in three regions".

"The dermal matrix market in Taiwan has good potential for us in reconstructive surgery, trauma and burns," Mr Brennan said.

Polynovo was up 22 cents or 8.7 percent to \$2.74 with 6.6 million shares traded.

[PAINCHEK](#)

Painchek says it has extended its partnership with Montreal healthcare software provider Alayacare to sell its pain assessment tool in Canada.

Painchek said it would pay fees to Alayacare for the integration of its technology into Alayacare's home care software platform and for lead generation and marketing support.

The company said it would remain responsible for direct sales, implementation, training and technical support in Canada and it would begin sales on regulatory clearance, which was expected by the end of 2020.

Painchek was up 0.2 cents or 2.2 percent to 9.2 cents with 1.35 million shares traded.

RESAPP HEALTH

Resapp says it has launched its Resappdx smart phone respiratory diagnostic application on Samsung Galaxy S9, S10 and S20 mobile telephones.

In July, Resapp said it had two-year service and software agreements with CoviU Global and Phenix Health to add its Resappdx-EU respiratory diagnostic to their telehealth platforms (BD: Jul 1, 2020).

Today, the company said the launch followed extensive internal testing, it expected to make Resappdx available on the CoviU platform next week and it would work with Phenix Health to update the Android version of their telehealth application.

Resapp said its mobile phone application analyzed cough sounds and could be used by clinicians to diagnose lower respiratory tract disease, croup, pneumonia, asthma and reactive airway disease exacerbation, chronic obstructive pulmonary disease exacerbation and bronchiolitis.

The company said it expected an Android launch of its Sleepcheck by 2021.

Resapp was up one cent or 9.5 percent to 11.5 cents with 4.3 million shares traded.

GENETIC SIGNATURES

Perennial Value Management says it has increased its substantial shareholding in Genetic Signatures from 13,399,698 shares (9.40%) to 19,259,534 shares (13.48%).

The Sydney-based Perennial said that it bought and sold shares between April 1 and October 23, 2020, with the single largest sale 1,260,651 shares for \$2,364,225 or \$1.88 a share on September 22, 2020 and the single largest purchase 1,112,305 shares for \$2,086,017 or \$1.88 a share on the same day.

Genetic Signatures was up two cents or one percent to \$1.99.

RHINOMED

Dr John McBain, Picton Cove and Fifty-Second Celebration say they have increased their holding in Rhinomed from 35,752,640 shares (14.09%) to 38,853,927 shares (15.11%).

The Melbourne-based Dr McBain said that between October 16 and 27, 2020 Fifty-Second Celebration acquired 2,602,944 shares for \$442,805 or 17.0 cents a share.

Rhinomed was up three cents or 22.2 percent to 16.5 cents.

IMPEDIMED

Impedimed says all resolutions at its annual general meeting passed easily, but 16.23 percent of votes opposed the additional 10 percent placement capacity.

Impedimed said there were 68,277,457 votes (16.23%) against the placement capacity, with 352,460,225 votes (83.77%) in favor.

The company said the remaining 15 resolutions passed with more than 97 percent approval.

According to Impedimed's most recent Appendix 2A new issue announcement, the company had 1,073,840,169 shares on issue, meaning the 68,277,457 votes against the placement capacity amounted to 6.4 percent of the company, sufficient to call extraordinary general meetings.

Impedimed was up 0.2 cents or 2.3 percent to 8.9 cents with 5.2 million shares traded.

RACE ONCOLOGY

Race says its annual general meeting will vote to issue up to 5,600,000 options to directors Phillip Lynch, Prof Borje Andersson and Dr Daniel Tillett.

Race said it would vote to issue up to 2,000,000 options each to Mr Lynch and Dr Tillett and up to 1,600,000 options to Prof Andersson, exercisable at a 48 percent premium to the 10-day volume weighted average price within five years.

The company said a third of the options would vest 12 months from the issue date, 2.78 percent would vest on each month for 23 months and 2.78 percent would vest 24 months from the first vesting date.

Race said it would vote to issue 118,577 performance rights to Prof Andersson as an incentive, vesting upon recruitment of the tenth patient in its phase IIb trial of Bisantrone. The company said it would also vote to adopt its remuneration report, elect Prof Andersson, Mr Lynch and Dr John Cullity directors, adopt its incentive performance rights plan, replace its constitution, approve the 10 percent placement capacity and ratify the prior issue of shares.

The virtual meeting will be held on November 30, 2020 at 9am (AEDT) with registration at: https://us02web.zoom.us/webinar/register/WN_BInP31oWSMWvV0c5rf-6-Q.

Race fell 4.5 cents or 4.3 percent to \$1.005.

AUSCANN GROUP HOLDINGS

Auscann says it has appointed Kidder Williams for business advice, appointed a medical advisory board and has suspended its unmarketable parcel facility.

Auscann said it had appointed Kidder Williams to explore potential strategic growth opportunities, including acquisitions in the medical marijuana sector.

The company said it had appointed its chief medical advisor Dr Marc Russo to chair the new medical advisory board, with Dr Peter Georgius, Prof Peter Gonski and Dr Sachin Shetty appointed as board members.

Auscann said Dr Georgius was an expert in complex pain conditions and Prof Gonski was a senior staff specialist geriatrician and director of Southcare at Sutherland Hospital and Community and the clinical stream director of aged care and rehabilitation and a board member for South Eastern Sydney Local Health District.

The company said Dr Shetty was a rehabilitation and pain physician and held key positions at Prince of Wales public and private hospitals.

In July, Auscann said it had a share sale facility for holders of unmarketable parcels of shares, which would close on September 4, 2020 (BD: Jul 17, 2020).

Today, the company said 500,000 shares had been sold through the facility to date, with 9,535,679 shares remaining to be sold and it would suspend the facility due to the Kidder Williams appointment until the review had been completed.

Auscann said it would allow shareholders to take back their shares by opting out of the facility by December 11, 2020 for an expected facility close by the end of February 2021.

Auscann was up half a cents or 3.7 percent to 14 cents.

HYDRIX

Hydrix has requested a trading halt pending "a material announcement to the market in relation to a proposed capital raising by way of a placement".

Trading will resume on November 3, 2020 or on an earlier announcement.

Hydrix last traded at 32.5 cents.

AUSBIOTECH

Ausbiotech says it has appointed Biocurate chief operating officer and company secretary Linda Peterson as a director at its annual general meeting.

Ausbiotech said Ms Peterson had more than 30 years' experience and was previously the executive manager of the Bionics Institute and the chief executive officer of Bionic Enterprises.

The organization said the board's chair was Michelle Burke, the managing-director was Lorraine Chiroiu with directors including Serg Duchini, Dr Jan Tennent, Dr Dean Moss, Dr Serge Scrofani and Ms Peterson.

RACE ONCOLOGY

Race says non-executive directors Dr Bill Garner and Chris Ntoumenopoulos have resigned.

Dr Garner said they were stepping down "given the time commitments required of other ventures that we're each involved with".