



Biotech Daily

Monday July 13, 2020

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: AMPLIA UP 19%; USCOM DOWN 20%
- * AVITA: BARDA ORDERS \$13.2m RECELL SYSTEMS
- * USCOM CUSTOMER RECEIPTS UP 59% TO \$4m
- * CORRECTION: CYNATA THERAPEUTICS
- * MTP TO RUN FEDERAL \$47m DIABETES, C-V PROGRAM
- * FEDERAL \$50k FOR PATRYS, ONJCRI PAT-DX1 FOR BREAST CANCER
- * RACE: WILLIAMS, EMMANUEL, MERCHANT COMMIT TO \$3m
- * LUINA, XING WORK ON POINT-OF-CARE SARS-COV-2 TEST
- * IMAGION JOINS BOSTON UNI'S NANOSYSTEMS RESEARCH CENTRE
- * CLINUVEL: PRENUMBRA FOR UNNAMED ACUTE, SYSTEMIC DISEASES
- * HERAMED: READY FOR JOONDALUP HERABEAT TRIAL
- * LBT APPOINTS ONESERVICE APAS SERVICE PROVIDER
- * PHARMAUST: MONEPANTEL DOG CANCER TRIAL REPORT WITH ELANCO
- * AVECHO: 31% OPPOSITION TO EQUITY INCENTIVE PLAN
- * LIVING CELL TELLS ASX: 'NOT MATERIAL INFO SENT PRICE 50%'
- * CANN GLOBAL RELEASES 706m SHARES FROM ASX ESCROW
- * NUHEARA 6m DIRECTOR OPTIONS AGM
- * ZELIRA ISSUES 12.5m CHAIRMAN, DIRECTOR PERFORMANCE RIGHTS
- * REGAL FUNDS REDUCES TO 5% OF MEDICAL DEVELOPMENTS
- * JAMBER, JAMES SCHWARZ SELLS ALL 10m ESENSE SHARES
- * CHIFLEY REDUCES TO 8.7% OF ESENSE
- * COCHLEAR LOSES CFO BRENT CUBIS; CFO WANTED
- * INVION APPOINTS MELANIE LEYDIN CFO; MELANIE FARRIS DIRECTOR

MARKET REPORT

The Australian stock market was up 0.98 percent on Monday July 13, 2020, with the ASX200 up 58.3 points to 5,977.5 points. Seven of the Biotech Daily Top 40 stocks were up, 26 fell and seven traded unchanged. All three Big Caps fell.

Amplia was the best, up two cents or 19.05 percent to 12.5 cents, with 224,229 shares traded. Alterity climbed 11.4 percent; LBT improved 8.8 percent; Resonance rose 3.2 percent; with Next Science, Osprey and Pharmaxis up by more than two percent.

Last Friday's 7.8 percent best, Uscom, led the falls, down 5.5 cents or 20 percent to 22 cents, with 2.4 million shares traded.

Avita lost 9.4 percent; Nova Eye (Ellex) was down 6.6 percent; Mesoblast shed 5.2 percent; Actinogen, Clinuvel, Compumedics, Neuren, Paradigm, Prescient, Starpharma and Telix fell four percent or more; Cyclopharm, Dimerix, Immutep, Impedimed, Nanosonics, Polynovo, Pro Medicus and Universal Biosensors were down three percent or more; Kazia and Opthea shed more than two percent; Medical Developments, Proteomics and Volpara fell more than one percent; with Cochlear, CSL, Genetic Signatures and Resmed down by less than one percent.

AVITA THERAPEUTICS

Avita says the US Government has ordered \$US9.2 million (\$A13.2 million) of Recell systems for public health preparedness and emergencies.

Avita said that the US Biomedical Advanced Research and Development Authority (BARDA) would purchase, store and deliver the Recell spray-on-skin system for \$US7.6 million through a "vendor managed inventory" plan and it had expanded the contract for \$US1.6 million in supplemental funding to support emergency deployment in mass casualty or other emergency situations.

The company said it expected to begin delivery later this year.

BARDA acting director Gary Disbrow said the group's mission was "to secure medical counter-measures needed to save lives in public health emergencies which means we continually work to prepare for any potential threats, whether natural or intentional, that could result in mass injuries".

Avita chief executive officer Dr Mike Perry said the company was "very pleased to continue collaborating with BARDA to ensure healthcare providers have access to the Recell system to help patients in large-scale emergencies".

"The ongoing preparation from BARDA underscores the importance of public-private partnerships in advancing biomedical innovation to address unmet medical needs," Dr Perry said.

Avita fell 74 cents or 9.4 percent to \$7.14 with 1.7 million shares traded.

USCOM

Uscom says receipts from customers for the 12 months to June 30, 2020 was up 58.9 percent to \$4,022,000 compared to the previous year.

Uscom said it has cash and cash equivalents of \$1,921,000 at June 30, 2020 compared to \$1,208,496 at June 30, 2019, and 5.5 quarters of cash.

Uscom fell 5.5 cents or 20 percent to 22 cents with 2.4 million shares traded.

CORRECTION: CYNATA THERAPEUTICS

Friday's edition incorrectly said that graft-versus-host disease occurred when the recipient body rejected the 'alien' marrow.

In fact, GvHD occurs when the donor's T-cells view the patient's healthy cells as foreign and attack them.

The Friday sub-editor has been sent back to medical school for retraining.

Cynata was unchanged at 62 cents.

MTP CONNECT

MTP Connect says it will run a \$47 million Federal Government Targeted Translation Research Accelerator initiative for diabetes and cardio-vascular disease.

MTP Connect said the program would establish research centres for diabetes and cardiovascular disease, a contestable funding program to support research projects and would promote clinical and commercial translation of therapeutics and devices.

The company said the Accelerator would be guided by a board appointed by the Federal Minister for Health Greg Hunt and would work in partnership with leading diabetes and cardiovascular disease groups.

MTP Connect chief executive officer Dr Dan Grant said that the program would "stimulate collaboration across relevant industry, research and clinical organizations and leverage strengths across the sector to ultimately produce novel preventative interventions, diagnostic and therapeutic approaches and products for diabetes and cardiovascular disease that reduce the burden on patients, families and communities".

"The [Targeted Translation Research Accelerator] program will drive a new focus on research efforts for the most pressing areas of unmet clinical and research needs in diabetes and cardiovascular disease, which are leading causes of death and disability in Australia," Dr Grant said.

MTP Connect chair Sue MacLeman said that the program would establish research centres for diabetes and cardio-vascular disease provide funding support and promote clinical and commercial translation.

MTP Connect said the funding was provided through the Government's Medical Research Future Fund.

PATRY'S, FEDERAL GOVERNMENT

Patrys says it has a \$50,000 Federal Government for research on PAT-DX1 for breast cancer at Melbourne's Olivia Newton-John Cancer Research Institute.

Patrys said the funding would further inform PAT-DX1 as a treatment for metastatic breast cancer with DNA damage repair defects through in vivo studies to assess efficacy in combination with standard-of-care radio and chemotherapies.

The company said the research, led by the Institute's head of translational breast cancer, Prof Robin Anderson, would focus on understanding the genetic regulation of metastasis and aimed to identify new targets for molecular-based therapy for progressive disease patients.

Patrys said it had planned an ongoing collaboration to investigate the ability of PAT-DX1 to "reach distant sites of breast cancer metastasis", which would be expanded to include its nanoparticle conjugated form PAT-DX1-NP and anticipated new formats of the deoxymab platform.

Patrys was unchanged at 1.2 cents.

RACE ONCOLOGY

Race says it has commitments to raise \$3 million through a strategic placement at 60 cents a share to three biotechnology investors.

Race said the investors included Kidder Williams' David Williams, EFM Asset Management's Jeff Emmanuel and Merchant Opportunities Fund.

The company said the issue price was at a 1.96 percent discount to the 15-day volume weighted average price, but its share price climbed 138 percent over the past 30 days.

Race said the funds would be used for a phase II combination trial of Bisantrone for acute myeloid leukemia, planned for late 2020.

Race was up 19 cents or 24.5 percent to 96.5 cents with three million shares traded.

LUINA BIO

Luina says it will work with Xing Technologies to co-develop and manufacture a point-of-care test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Luina chief executive officer Les Tillack told Biotech Daily that the lateral flow assay test used antibodies to detect the virus protein with results available in 15 minutes.

In a media release, the Brisbane-based Luina said that the test was based on a temperature-stable molecule using Xing technology.

In March, Luina said it had a memorandum of understanding with Brisbane's Griffith University for the development of a coronavirus vaccine, to use Luina's "wealth of contract manufacture capabilities and experience" (BD: Mar 19, 2020).

Today, the company said that Brisbane's Xing wanted "to fast-track the development and regulatory approval of the diagnostic kit to meet customer needs in US, Europe and the pan-Asian region".

Luina said the customers wanted "a fast and accurate point-of-care antigen test as a superior alternate to existing serology tests which measure immune response".

The company said the test would detect the live virus, with Luina developing and implementing the manufacturing of key protein reagents in yeast, central to the Xing test.

Mr Tillack said that the "estimated time to [good manufacturing practice] production using the Luina [flexible bio-manufacturing platform] systems will only take 24 weeks from project commencement to completion".

"Flexibility is key to being able to respond to important rapid development programs like this," Mr Tillack said.

Luina is a private company.

IMAGION BIOSYSTEMS

Imagion says it has joined Boston University's Nanosystems Engineering Research Centre developing magnetic sensors, which could simplify its Magsense system.

Imagion said that as a member of the Centre, it would have priority access to new cellular meta-materials technologies, which primarily focused on advancing nano-bio-manufacturing methods.

The company said it was particularly interested in advancements in the use of micro-electro-mechanical systems as ultra-sensitive magneto-meters, which could improve detection of cardiovascular events and biomedical imaging.

Imagion said the sensors could eliminate the need to use cryogenically cooled sensors, which would significantly reduce the size and cost of its Magsense system and enable the use of Magsense in a doctor's suite and hospital imaging suite.

Imagion was up 0.1 cents or 2.3 percent to 4.4 cents with 22.2 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will begin a clinical development program to evaluate Prenumbra, a liquid form of afamelanotide for acute and systemic disease.

Clinuvel has US and European approvals for Scenesse, a slow release, sub-cutaneous injected version of 16mg afamelanotide for erythropoietic protoporphyria (EPP).

Clinuvel said Prenumbra would be assessed as a haemodynamic vasoactive and anti-oncotic, or colloid osmotic, therapeutic agent, initially for adults with vascular anomalies and oedema.

The company said Prenumbra would be evaluated on patients where corticosteroids and other anti-inflammatory drugs had not been successful or had caused drug dependency or severe side effects.

Clinuvel said the safety profile and effectiveness of afamelanotide had previously been established, including as Scenesse product for EPP.

The company said it had intellectual property rights and international trademarks for Prenumbra for unnamed identified indications.

Clinuvel fell 97 cents or 4.1 percent to \$22.54 with 197,892 shares traded.

HERAMED

Heramed says it has approval to begin a trial of its Herabeat foetal and maternal pregnancy heart rate monitor at Perth's Joondalup Health Campus.

Heramed said the study would evaluate the usability, accuracy and reliability of the Herabeat device for remote pregnancy monitoring, initially at an antenatal clinic and then at home.

The company said it would provide the technology, support and instructions for best practice usage and clinicians at the Joondalup Health Camus would be responsible for planning, leadership, execution, and recruitment.

Heramed said it was undergoing registration on the Australia and New Zealand Clinical Trials registry and it would begin recruitment "shortly".

Heramed was up 0.2 cents or 2.2 percent to 9.3 cents with 1.3 million shares traded.

LBT INNOVATIONS

LBT says it has appointed Oneservice AG as the service provider for its automated plate assessment system (APAS) Independence in Europe and the US.

LBT said that the Feusisberg, Switzerland-based Oneservice would be responsible for instrument installation and in-field maintenance services for each APAS instrument sold.

LBT was up 1.5 cents or 8.8 percent to 18.5 cents with 1.7 million shares traded.

PHARMAUST

Pharmaust says it has delivered the final report on its phase II monepantel dog cancer trial to the US-based Eli Lilly subsidiary Elanco.

In 2018, Pharmaust said it had an option agreement with Elanco, through which Elanco would supply monepantel for clinical trials and would have six months following receipt of the final report to take up a royalty-bearing commercial licence to use its intellectual property for cancer in animals (BD: Apr 18, 2018).

The company said it would have a further six months to negotiate for an agreement.

Pharmaust fell 1.5 cents or seven percent to 20 cents with three million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says its annual general meeting has passed five of six resolutions easily, but with 30.6 percent opposition to the equity incentive plan.

Avecho said 125,277,031 votes (30.64%) opposed the plan, with 283,559,295 votes (69.36%) in favor.

According to the company's annual report for the year to December 31, 2019, it had 1,577,457,420 shares on offer, meaning the opposition to the equity incentive plan amounted to 7.94 percent, sufficient to call extraordinary general meetings.

Avecho fell 0.1 cents or 12.5 percent to 0.7 cents with 5.2 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that a newsletter discussing its obesity and migraine programs was not material despite a 50 percent share price increase.

The ASX asked whether the announcement, titled 'LCT Newsletter', lodged on July 3, 2020 disclosing an update on the development and progress of the company's research projects into the treatment of migraine and obesity was material.

The ASX asked Living Cell when the company became aware of the information and said the company's share price climbed 0.6 cents or 50 percent from 1.2 cents to 1.8 cents on July 3, noting "a significant increase" in the volume of shares traded.

Living Cell said that "the only new information contained in the company's Newsletter ... related to the reopening of the University labs" and that the team at the University of Auckland had resumed work on the migraine project.

The company said it did "not consider the information to be information that a reasonable person would expect to have a material effect on the price or value of its securities".

Living Cell said the University of Auckland research suspension "would only ever impact timing of the research and not outcomes: and lifting of Covid-19 restrictions in New Zealand from midnight on June 8 made clear that the suspension would be short term".

"In the event, by 22 June, when [Living Cell] was made aware that one animal had been treated with no results known, the suspension of research work was in fact of short duration," the company said.

Living Cell said that the suspension of research did not affect other project related activities.

The company told the ASX that the newsletter was not marked "price sensitive [and] had the information been price sensitive, it would have been released immediately it was known in a separate announcement".

Living Cell told the ASX that it had intended to start a phase I trial of LP-003 for obesity by the end of 2020 but "due to the Covid-19 lockdown in New Zealand, this has been delayed".

The company said that the "obesity study was delayed due to the Covid-19 lockdown as previously advised to the market, and it continued to be delayed".

Living Cell was up 0.2 cents or 15.4 percent to 1.5 cents with 2.2 million shares traded.

CANN GLOBAL

Cann Global says it will release 705,804,687 shares from ASX escrow on July 19, 2020.

According to Cann Global's most recent Appendix 2A, the company will have 2,848,955,456 shares on issue following the release of shares, with a further 541,033,587 shares remaining in ASX escrow until August 23, 2021.

Cann Global fell 0.1 cents or 16.7 percent to 0.5 cents with 3.6 million shares traded.

[NUHEARA](#)

Nuheara says an extraordinary general meeting will vote to issue 3,000,000 options each to chair Cheryl Edwardes and non-executive director David Buckingham.

Nuheara said the options would be “a non-cash form of remuneration” exercisable in two tranches at 25 cents an option and 10 cents an option.

The company said it would also vote to ratify the prior issue of one convertible note and 12,500,000 shares, 24,264,706 options and 20,000,000 further shares to Lind Global Macro Fund, issued through a 24-month, \$2,500,000 funding.

Nuheara said the meeting would vote to ratify the prior issue of 88,235,294 placement shares and 3,750,000 share purchase plan underwriter options and to adopt its employee share and salary sacrifice plan and employee incentive option plan.

The meeting will be held at 190 Aberdeen Street, Northbridge, Western Australia on August 14, 2020 at 9am (AWST, 11am AEST).

Nuheara was up 0.9 cents or 33.3 percent to 3.6 cents with 56.7 million shares traded.

[ZELIRA THERAPEUTICS](#)

Zelira says it will issue 12,500,000 performance rights to chairman Osagie Imasogie and non-executive director Lisa Gray.

Zelira said the rights would be issue in two equal tranches of 6,250,000 class A and class B performance rights at \$US1 million and \$US2,500,000 revenue milestones by December 23, 2024.

The company said this would provide for a performance-based remuneration package consistent with other non-executive directors.

Zelira fell 0.3 cents or 5.2 percent to 5.5 cents with 1.7 million shares traded.

[MEDICAL DEVELOPMENTS INTERNATIONAL](#)

Regal Funds Management says it has reduced its substantial shareholding in Medical Developments from 3,973,464 shares (6.05%) to 3,307,076 shares (5.04%).

The Sydney-based Regal Funds said that between June 12 and July 8, 2020 it bought 16,144 shares for between \$6.60 and \$8.12 a share and sold 682,532 shares for between \$6.78 and \$8.18 a share.

Medical Developments fell 12 cents or 1.8 percent to \$6.46 with 337,880 shares traded.

[ESENSE-LAB](#)

Jamber Investments says it has ceased to be a substantial shareholder in Esense.

Last October, the Vacluse, New South Wales-based James Schwartz and Jamber said that they had become substantial with 10,000,000 shares or 5.27 percent of the company, buying the shares for an average 1.7 cents a share (BD: Oct 24, 2019).

Today, Jamber said that on July 7, 2020 it disposed of all 10,000,000 Chess depositary interests (CDIs) for \$439,999.99 or 4.4 cents a share.

Esense was unchanged at two sense with 60.3 million shares traded.

[ESENSE-LAB](#)

Chifley Portfolios says it has reduced its substantial shareholding in Esense from 62,500,000 Chess depositary interests (CDIs) (12.2%) to 44,500,000 CDIs (8.7%). The Sydney-based Chifley said that on July 7, 2020 it sold 21,928,701 shares for \$710,805.35 or 3.2 cents per CDI and bought 3,928,701 shares for \$90,142.49 or 2.3 cents per CDI.

[COCHLEAR](#)

Cochlear says chief financial officer since March 2017, Brent Cubis, has resigned and will depart by December 31, 2020.

Cochlear chief executive officer Dig Howitt said the company thanked Mr Cubis for strengthening the finance function and “for his valuable contributions ... which include improving working capital management and his role in the recent capital raise”.

The company said it had begun an executive search for a replacement.

Cochlear fell \$1.47 or 0.8 percent to \$189.00 with 238,761 shares traded.

[INVION](#)

Invion says it has appointed Melanie Leydin as chief financial officer replacing director Melanie Farris who continues as a director and company secretary, effective immediately. Invion said Ms Leydin had more than 25 years’ experience and was the principal of the Melbourne-based chartered accounting firm Leydin Freyer.

The company said Ms Leydin was a member of the Institute of Chartered Accountants, a fellow of the Governance Institute of Australia and was a registered company auditor.

Invion said Ms Leydin held a Bachelor of Business from Swinburne University.

Last year, Invion appointed then chief financial officer and company secretary Melanie Farris as a director, replacing Dr James Campbell, and said that her financial management duties would transition to Leydin Freyer (BD: Jan 19, 2020).

Ms Farris continues as a director of Invion and the company secretary.

Invion fell 0.1 cents or 9.1 percent to one cent with 4.85 million shares traded.