

Biotech Daily

Thursday February 24, 2022

Daily news on ASX-listed biotechnology companies

* WAR DRAGS ASX, BIOTECH DOWN: PATRYS UP 4%; MICRO-X DOWN 17.5% * NEXT SCIENCE RAISES \$10m, PLAN FOR \$5m MORE * JAPAN APPROVES AVITA RECELL SYSTEM * TRAJAN H1 REVENUE UP 17% TO \$44m. PROFIT DOWN 95% TO \$153k * COGSTATE H1 REVENUE UP 67% TO \$32m; LOSS TO \$5.7m PROFIT * AUSTCO H1 REVENUE UP 15% TO \$16m, PROFIT UP 83% TO \$1.5m * CYCLOPHARM REVENUE UP 21% TO \$18m, LOSS DOWN 17% TO \$5m * ALTHEA H1 REVENUE UP 84% TO \$9.4m, LOSS DOWN 14.85% TO \$7m * VISIONEERING REVENUE UP 40% TO \$10m, LOSS DOWN 75% TO \$3.2m * TELIX REVENUE UP 46% TO \$7.6m, LOSS UP 79% TO \$80.5m * ACRUX H1 REVENUE UP 80% TO \$2m, LOSS DOWN 30% TO \$5.5m * GENETIC TECHNOLOGIES H1 REVENUE UP TO \$2m; LOSS UP 12% TO \$3.9m * MICRO-X H1 REVENUE DOWN 40% TO \$1.45m, LOSS UP 87% TO \$9m * USCOM H1 REVENUE DOWN 52% TO \$1.1m, LOSS UP 250% TO \$943k * ENA, COPD FOUNDATION PARTNER FOR PAN-ANTIVIRAL NASAL SPRAY * MTP CONNECT ADELAIDE BIOMED CITY 'INNOVATION INTERMEDIARY' * ZELIRA TO BUY HEALTH HOUSE FOR SCRIP; \$1.5m LOAN * ARGENICA COMPLETES ARG-007 GENOTOXICITY STUDIES * HYDRIX REQUESTS 'CAPITAL RAISING' TRADING HALT * CRESO TAKES 'CAPITAL RAISING' TRADING HALT TO SUSPENSION * ANTISENSE, CHICAGO'S NORTHWESTERN WORK ON 'LONG COVID' * STARPHARMA APPOINTS EX-CSL EXECUTIVE DR JEFF DAVIES DIRECTOR

MARKET REPORT

The Australian stock market fell 2.99 percent on news of Russia invading Ukraine on Thursday February 24, 2022. The ASX200 lost 215.1 points to 6990.6 points. Thirty-seven Biotech Daily Top 40 stocks fell, two rose, one traded unchanged and all Big Caps fell.

Patrys was the better of the two, up 0.1 cents or 4.35 percent to 2.5 cents, with 2.2 million shares traded. Genetic Signatures rose two percent and Uscom was untraded.

Micro-X led the falls, down 3.5 cents or 17.5 percent to 16.5 cents, with 3.2 million shares traded. Clinuvel fell 17.3 percent; Imugene lost 15.4 percent; Amplia, Compumedics and Impedimed were down more than 13 percent; Kazia lost 12 percent; Next Science and Pharmaxis were down more than 11 percent; both Antisense and Resonance fell 10.3 percent; Actinogen, Alcidion and Prescient shed more than nine percent; Immutep lost 8.45 percent; Emvision, Orthocell and Polynovo lost seven percent or more; Oncosil, Paradigm and Volpara were down more than five percent; Neuren, Opthea and Telix fell more than four percent; Atomo, Avita, Nanosonics, Nova Eye and Pro Medicus lost more than three percent; Cyclopharm, Cynata, Dimerix, Mesoblast, Resmed and Universal Biosensors shed more than two percent; Cochlear, CSL and Starpharma lost more than one percent, with Medical Developments and Proteomics down less than one percent.

NEXT SCIENCE

Next Science says it has raised \$10 million in a placement at 90 cents a share and hopes to raise a further \$5 million in a share plan.

Next Science said that the funds would support its commercial rollout and further clinical program development for Xperience and working capital.

The company said the price was a 12.6 percent discount to the last closing price and a 15.5 percent discount to the 5-day volume-weighted average price, and major shareholder Lang Walker had committed \$4 million to the placement.

The company said the share plan would be at the lower of 90 cents or a two percent discount to the 5-day volume-weighted average price to the plan's closing date, the record date was February 23, it would open on March 4 and close on March 23, 2022. The company said the placement was managed by Canaccord Genuity and Wilsons. Next Science fell 12 cents or 11.65 percent to 91 cents.

AVITA MEDICAL

Avita says Japan's Pharmaceuticals and Medical Devices Agency has approved the marketing of the Recell skin harvesting and spray-on skin system in Japan. Avita said that M3 Group company, the Tokyo-based Cosmotec, "championed the approval and [was its] distribution partner".

Avita chief executive officer Dr Mike Perry said the company was "excited about the opportunity this approval provides in enabling the Rrecell system to be made available to Japanese medical institutions to treat patients with burns requiring skin grafting".

"Japan is the second largest healthcare market in the world and represents a valuable opportunity for our company with more than 6,000 patients treated for severe burns annually who will now have access to this innovative treatment option," Dr Perry said. The company said the device used "a small amount of a patient's own skin, to treat severe burns, while reducing the amount of donor skin required" and was designed to be used at the point-of-care alone or in combination with autografts depending on the injury. Avita fell nine cents or 3.6 percent to \$2.40 with 480,309 shares traded.

<u>TRAJAN</u>

Trajan says revenue for the six months to December 31, 2021 was up 16.8 percent to \$43,712,000 with net profit after tax down 95.3 percent to \$153,000.

Trajan said revenue came from the sales of its medical and scientific analysis products, with its Life Sciences Solutions human health range growing 22.5 percent over the period. The company said the fall in profit was due to business acquisition expenses, commercialization costs and restructuring.

Trajan listed on the ASX on June 7, 2021, and today said its diluted earnings per share at December 31, 2021 was 0.1 cents with net tangible assets per share of 19 cents. Trajan said it had cash and cash equivalents of \$33,082,000 at December 31, 2021

compared to \$11,098,000 at December 31, 2020.

Trajan fell 16 cents or 4.85 percent to \$3.14.

COGSTATE

Cogstate says revenue for the six months to December 31, 2021 was up 66.5 percent to \$US23,075,459 (\$A32,070,042) with last year's loss turned to a profit of \$US4,083,202 (\$A5,674,793).

Cogstate said revenue came primarily from its cognitive tests for clinical trials and the healthcare market, both of which showed strong revenue growth, with healthcare increasing 93 percent.

The company said last year's diluted loss per share of 0.3 US cents was turned to diluted earnings per share of 2.2 cents, net tangible asset backing per share was up from negative 0.2 US cents to 8.6 US cents and it had cash and equivalents of \$US25,336,663 at December 31, 2021 compared to \$US21,329,622 at December 31, 2020. Cogstate fell two cents or 1.1 percent to \$1.79.

AUSTCO HEALTHCARE

Austco says revenue for the six months to December 31, 2021 was up 14.7 percent to \$15,953,000 with net profit after tax up 82.9 percent \$1,511,000.

Austco said its revenue came from sales of its Tacera, Pulse and Medicom branded healthcare communications and caregiver clinical workflow systems.

The company said diluted earnings per share was up 81.7 percent to 0.527 cents with net tangible assets per share up 26.1 percent to 5.56 cents, and cash and cash equivalents of \$7,074,000 at December 31, 2021 compared to \$6,340,000 at December 31, 2020. Austco was up half a cent or four percent to 13 cents.

<u>CYCLOPHARM</u>

Cyclopharm says revenue for the year to December 31, 2021 was up 20.6 percent to \$17,704,574 with net loss after tax down 16.6 percent to \$5,040,166.

Cyclopharm said revenue came primarily from sales of its Technegas lung imaging generators and patient administration sets.

The company said that an unfranked interim dividend of 0.5 cents a share for shareholders on the record date of April 5 would be paid on April 12, 2022.

Cyclopharm said diluted loss per share was down 28.6 percent to 5.63 cents with net tangible assets per share up 166.7 percent to 40 cents, and cash and cash equivalents of \$29,249,255 at December 31, 2021 compared to \$1,874,285 at December 31, 2020. Cyclopharm fell three cents or two percent to \$1.45.

ALTHEA GROUP HOLDINGS

Althea says revenue for the six months to December 31, 2021 was up 84.0 percent to \$9,380,000 with net loss after tax down 14.85 percent to \$7,045,000.

Althea said revenue came from its sales and distribution of medical marijuana products in Australia, the UK and Canada, predominantly through its Concierge online prescription platform.

The company said diluted loss per share was down 31.4 percent to 2.40 cents with net tangible backing per share up 1.0 percent to 8.76 cents.

Last year, the company said that net tangible asset backing per share was 10.14 cents (BD: Feb 25, 2021).

Last year, Althea said it had raised \$10.64 million in a placement at 24 cents a share for its marijuana products (BD: Aug 25, 2021).

Today, Althea said it had cash and cash equivalents of \$9,874,000 at December 31, 2021 compared to \$8,644,000 at December 31, 2020.

Althea fell two cents or 10.3 percent to 17.5 cents with one million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says revenue for the year to December 31, 2021 was up 40.1 percent to \$U\$7,154,000 (\$A9,943,000) with net loss after tax down 74.7 percent to \$U\$2,334,000 (\$A3,244,000).

Visioneering said revenue was from sales of its Naturalvue multifocal one-day contact lenses.

The company said that diluted loss per share fell 91.1 percent from \$US1.24 to 11 US cents.

Visioneering said that net tangible asset backing per Chess depositary interest (CDI) was 41.1 US cents compared to last year's negative 20.5 US cents.

Last year, Visioneering said net tangible asset backing per CDI was 0.2 cents, and that diluted loss per share was 1.0 US cents (BD: Feb 18, 2021).

The company said it had cash and cash equivalents of \$US10,985,000 at December 31, 2021 compared to \$US2,408,000 at December 31, 2020.

Visioneering fell one cent or 1.4 percent to 70 cents.

TELIX PHARMACEUTICALS

Telix says revenue for the year to December 31, 2021 was up 45.7 percent to \$7,596,000 with net loss after tax up 79.4 percent to \$80,510,000.

Telix said that \$4,898,000 of the revenue came from the sales and licencing of its targeted radiation products, but that revenues had been lower than expected due to later than expected regulatory approval for its TLX591-CDx kits ofr imaging prostate cancer, with \$2,698,000 from research and development services.

The company said that diluted loss per share was up 62.9 percent to 28.5 cents with net tangible assets per share down from 6.4 cents to negative 19.0 cents.

Telix said it had cash and cash equivalents of \$22,037,000 at December 31, 2021 compared to \$77,945,000 at December 31, 2020.

Telix fell 23 cents or 4.54 percent to \$4.84 with 2.3 million shares traded.

<u>ACRUX</u>

Acrux says revenue for the six months to December 31, 2021 was up 80.1 percent to \$2,097,000 with net loss after tax down 29.7 percent \$5,473,000.

Acrux said its revenue came from sales of its transdermal drug delivery technologies, with Estradiol hormone replacement spray sales increasing 29 percent.

The company said diluted loss per share was down 56.7 percent to 1.93 cents with net tangible assets per share constant at 4.0 cents.

Acrux said it has cash and cash equivalents of \$10,596,000 at December 31, 2021 compared to \$11,461,000 December 31, 2020.

Acrux fell 0.2 cents or 2.1 percent to 9.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says revenue for the six months to December 31, 2021 was \$2,051,016, up from last year's \$16,436, with net loss after tax up 11.7 percent to \$3,881,371.

Genetic Technologies said revenue came primarily from sales of its EasyDNA paternity test and Genetype breast cancer and colorectal cancer products.

The company said last year's diluted loss per share was down 20 percent to 0.04 cents, with net tangible asset backing per share down 21.1 percent to 0.15, and cash of \$13,507,370 at December 31, 2021 compared to \$16,435,109 at December 31, 2020. Genetic Technologies was unchanged at 0.5 cents with 32.9 million shares traded.

MICRO-X

Micro-X says revenue for the six months to December 31, 2021 was down 40.4 percent to \$1,449,000 with net loss after tax up 87.3 percent to \$8,965,000.

Micro-X said revenue came from sales of its Caresteam DRX Revolution Nano and Rover mobile x-rays, with \$400,000 coming from the US Department of Homeland Security for the development of the Airport Self Screening and Portal programs.

The company said diluted loss per share was up 45.5 percent to 1.95 cents with net tangible asset backing per share up 221.4 percent to 4.5 cents.

Micro-X said it had cash and cash equivalents of 19,944,000 at December 31, 2021 compared to \$12,874,000 at December 31, 2020.

Micro-X fell 3.5 cents or 17.5 percent to 16.5 cents with 3.2 million shares traded.

<u>USCOM</u>

Uscom says revenue for the six months to December 31, 2021 was down 51.5 percent to \$1,110,093 with net loss after tax up 249.8 percent to \$943,290.

Uscom said that lower than expected revenue was due to the global Covid-19 pandemic and came primarily from sales of its Uscom1A ultra-sonic cardiac output monitor, Uscom BP+ blood pressure monitor, Spirosonic pulmonary function test and Ventitest ultrasonic ventilator calibration devices.

The company said diluted loss per share was up 200 percent to 0.6 cents with net tangible asset backing per share up 290 percent to 3.9 cents.

The company said it had cash and cash equivalents of \$5,537,036 at December 31, 2021 compared to \$2,278,159 at December 31, 2020.

Uscom was untraded at 9.5 cents.

ENA RESPIRATORY

Sydney's Ena says it will partner with the Miami, Florida-based COPD Foundation to develop its INNA-051 nasal spray for people with chronic lung diseases.

Ena said that INNA-051 was being developed to stimulate innate immunity and reduce the incidence and severity of respiratory viral infections, such as Covid-19, rhinovirus, or influenza in populations at-risk of complications that include individuals with chronic obstructive pulmonary disease (COPD).

The company said that INNA-051 was "a first-in-class broad-spectrum anti-viral innate immunomodulator for pre and post-exposure prophylaxis of respiratory viral infections, including Covid-19 in populations at-risk of complications".

Ena said the Foundation was a not-for-profit organization aiming to improve the lives of those affected by COPD, bronchiectasis and non-tuberculous mycobacterial lung disease. The company said that a 100-subject, phase I study showed that INNA-051 was well-tolerated, and last year, said it would conduct a 420-patient Covid-19 post-exposure prophylaxis study and a 120-patient influenza challenge (BD: Jul 20, Sep 30, 2021). Today, Ena said the phase II studies would begin "soon".

The company said that respiratory virus infections, especially rhinovirus (the common cold), respiratory syncytial virus and influenza were related to worsening of chronic lung conditions, including COPD and asthma and the incidence of respiratory virus was associated with acute exacerbations.

COPD Foundation chief scientific officer Dr Ruth Tal-Singer said that there was "an urgent need for treatments that prevent flare-ups triggered by viral infections".

"This fast-acting nasal spray could be used before or shortly after virus exposure to help the body respond faster and reduce the chances of complications," Dr Tal-Singer said. Ena co-founder and chief executive officer Dr Christophe Demaison said that people with chronic lung diseases "continue to be impacted not just by the Covid-19 pandemic but by the resurgence of other common respiratory viruses".

"There continues to be a need for convenient treatments that can be used over the winter months or after known short-term exposure to a respiratory virus, to reduce the incidence of acute exacerbations of patients with chronic lung diseases," Dr Demaison said. Ena is a private company.

MTP CONNECT

MTP Connect says it has been appointed to deliver innovation and translation intermediary services for the Adelaide Biomed City (ABMC) innovation district. MTP said that under the \$3 million South Australian Government initiative, it would work with the ABMC and its research, clinical and business partners to build collaborations and "realize the innovation potential of South Australia's health and biomedical industry sectors".

MTP Connect interim chief executive officer Stuart Dignam said the Federal Government funded organization's networks "uniquely position us to deliver the ABMC intermediary program". "Our focus over the next three-years will be on fostering collaboration, strategically building innovation capacity and attracting new talent and opportunity to South Australia."

"By connecting ABMC partners and South Australia's broader health and medical ecosystem to national and global opportunities, we'll elevate ABMC as a precinct of choice for innovators, researchers and clinicians focused on translation," Mr Dignam said. Mr Dignam says the team was ready to begin work in Adelaide, with recruitment for additional roles to commence shortly.

ZELIRA THERAPEUTICS

Zelira says it will acquire Health House International in scrip for 19.45 percent of the expanded company and lend Health House \$1.5 million.

Zelira said the purchase was conditional on due diligence and a formal scheme implementation deed, among other standard conditions.

The company said that "to assist with its working capital requirements ... (it) agreed to provide a \$1.5 million loan facility".

Zelira said it would issue shares to Health House giving it a 19.45 percent interest in the expanded Zelira, but did not value the Health House acquisition.

Zelira currently has 1,654,072,578 shares on offer and at today's closing price of 2.4 cents has a market capitalization of \$39.7 million dollars.

Biotech Daily calculates that to provide Health House 19.45 percent of the expanded company, Zelira would issue Health House 399,400,517 shares valued at \$9,585,612, but \$7,721,210 after allowing for the dilution.

Zelira chair Osagie Imasogie said the proposed acquisition would "provide Zelira with control of direct access to highly regulated European and other markets for its products".

"This transaction will also provide Zelira with direct access to [good manufacturing practice] manufacturing facilities in Europe that will further improve margins for our products and provide stronger control of our product life cycle," Mr Imasogie said. "In addition, this transaction will provide Zelira with control of direct access to high quality international standard clinical trial capabilities for our proprietary cannabinoid-based products," Mr Imasogie said. "This will materially improve the speed at which these products can obtain clinical validation, while improving the cost of such clinical trials." Zelira said that directors Harry Karelis and Tim Slate were Health House shareholders, with 6.38 percent and 0.67 percent, respectively, with Mr Karelis holding about 1.5 percent of the Health House performance shares on issue.

The company said it had established a transaction committee comprising the nonconflicted directors of Zelira to assess and negotiate the transaction, and neither Mr Karelis or Mr Slate individually or together control and are not directors of Health House. Zelira fell 0.1 cents or four percent to 2.4 cents with 3.3 million shares traded.

ARGENICA THERAPEUTICS

Argenica says genotoxicity studies of ARG-007 to reduce brain tissue death after brain injury show the drug is safe for mutagenicity and structural chromosomal aberrations. Argenica said that the good laboratory practice genotoxicity studies by the Medicilon contract research organization tested ARG-007 for mutagenicity and predicted genetic risks and potential carcinogenic effects with all test results negative.

The company said that Medicilon chromosomal aberration test showed that ARG-007 did not cause structural chromosomal aberrations in cultured mammalian cells.

Argenica said that all genotoxicity studies required for its phase I trial ethics submission had been completed and the data could be filed to the US Food and Drug Administration for an investigational new drug application.

Argenica chief executive officer Dr Liz Dallimore said the results showed that volunteers being administered ARG-007 would "have no effect on their DNA or chromosomes or cause cancer in any manner".

The company said the protocols for pre-clinical activities had been finalized and the dosing for the pharmaco-kinetics and toxicology studies begun, with the final application to Adelaide's Bellberry independent ethics committees to be filed by July 2022. Argenica was up three cents or 4.8 percent to 66 cents.

<u>HYDRIX</u>

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 February 28, 2022 or on an earlier announcement. Hydrix last traded at 12.5 cents.

CRESO PHARMA

Creso says it has requested a voluntary suspension to follow its capital raising halt. On Tuesday, Creso requested a trading halt "pending an announcement regarding a capital raising" (BD: Feb 22, 2022).

Today, the company said it requested a further extension until February 25, 2022 or on the release of an earlier announcement.

Creso last traded at 7.7 cents.

ANTISENSE THERAPEUTICS

Antisense says that it has an agreement to study the neurological aspects of 'long Covid-19' with the Chicago-based Northwestern Medicine Neuro-Covid clinic.

Antisense said that research would be led by Dr Igor Koralnik and would assess up to 7,000 plasma proteins in long Covid-19 patients.

The company said the study would look for blood disease markers to assess if patients were amenable to treatment including with its ATL1102, with results in mid-2022. Antisense said the cost of the agreement was "not considered financially material" and would be funded from existing cash reserves" but the arrangement was market sensitive. Antisense said that long neuro Covid-19 was hypothesized to follow severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) specific patho-physiological changes, with aberrant inflammatory disease and immune responses post-acute infection, similar to those with other viral infections including Epstein-Barr virus and chronic fatigue syndrome. The company said that patients who had Covid-19 while also infected with Epstein-Barr virus "were at an increased risk of memory loss and [Epstein-Barr virus] infection increases the risk of autoimmune diseases such as multiple sclerosis".

Antisense said that ATL1102 had "previously demonstrated biologic activity in multiple sclerosis patients".

Antisense fell 1.5 cents or 10.3 percent to 13 cents with 1.85 million shares traded.

STARPHARMA HOLDINGS

Starpharma says it has appointed former CSL executive Dr Jeff Davies as an independent non-executive director, effective from April 1, 2022.

Starpharma said that Dr Davies had more than 35 years of biopharmaceutical experience, holding executive roles at CSL, including Asia-Pacific region general-manager and head of plasma product research and development at CSL-Behring, in Switzerland. The company said that Dr Davies held a Doctor of Philosophy from Monash University and was a graduate of the London Business School's senior executive program. Starpharma fell 1.5 cents or 1.6 percent to 93.5 cents.