

Biotech Daily

Wednesday June 19, 2024

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: TELIX UP 4%; CYNATA DOWN 8%
- * FEDERAL \$8.3m TAKES QUT TO CARDIAC DEVICE PROGRAM
- * MACH7: DOCPANEL \$1.9m ENTERPRISE RENEWAL
- * ADHERIUM SIGNS MODIVCARE HAILIE DEAL
- * BIOTRON BIT-225 'PARTIAL IMMUNE' HIV TRIAL MEETS ENDPOINTS
- * MELODIOL 'MAY LEASEBACK MERNOVA PROPERTY'; \$5m NOTES
- * RECCE RECEIVES \$2.6m OFFSHORE FEDERAL R&D TAX INCENTIVE
- * BOTANIX REQUESTS 'SOFDRA FDA APPROVAL' TRADING HALT
- * PHARMAUST REQUESTS 'CAPITAL RAISING' TRADING HALT
- * HERAMED: 'RECORD 560 ACTIVE HERACARE USERS'
- * TRYPTAMINE APPOINTS LUCID HEALTH ADVISOR

MARKET REPORT

The Australian stock market fell 0.11 percent on Wednesday June 19, 2024, with the ASX200 down 8.4 points to 7,769.7 points.

Twelve of the Biotech Daily Top 40 were up, 20 were down, seven traded unchanged and one was untraded.

Telix was the best, up 75 cents or 4.4 percent to \$17.95, with 1.8 million shares traded. Atomo climbed 3.6 percent; Avita, Curvebeam, Impedimed and Orthocell improved more than two percent; Immutep, Pro Medicus and Resonance were up more than one percent; with Clinuvel, Genetic Signatures, Nanosonics and Resmed up by less than one percent.

Cynata led the falls, down 2.5 cents or 8.2 percent to 28 cents, with 75,025 shares traded. Amplia, Next Science and Prescient lost more than seven percent; Emvision and Paradigm were down more than six percent; Mesoblast and Proteomics fell more than four percent; Compumedics, SDI and Syntara were down more than three percent; Alcidion Cyclopharm, Dimerix, Medadvisor and Nova Eye shed two percent or more; Medical Developments and Starpharma were down more than one percent; with Cochlear, CSL Neuren and Polynovo down by less than one percent.

QUEENSLAND UNIVERSITY OF TECHNOLOGY. FEDERAL GOVERNMENT

Queensland University of Technology says it has received an \$8.3 million Federal Government grant to to develop implantable cardiac devices.

Earlier this year, the Federal Government said its Medical Research Future Fund (MRFF) would provide \$50 million to open the Artificial Heart Frontiers program for the development of three cardiac devices (BD: Feb 20, 2024).

Today, Queensland University of Technology said the Artificial Heart Frontiers program (AHFP) was led by Melbourne's Monash University and based at the Monash Alfred Baker Centre for Cardiovascular Research at Melbourne's Alfred Hospital.

The University said its program was led by AHFP co-director Prof Shaun Gregory and it would use the \$8.3 million to develop and commercialize the Minipump, an implant for mechanical circulatory heart support that required a minimally invasive surgery. QUT said that by 2036 the program was expected to generate a \$1.8 billion benefit to Australia, including "savings to the healthcare system, an expansion in local industry in research and manufacturing, the creation of more than 2,000 jobs, and providing Australians early access to clinical trials and emerging life-saving technologies". Prof Gregory said the Minipump would help patients with a "specific type of heart failure that at the moment is completely unaddressed, so it's a big priority for our team". "Central to the Frontiers Program is the creation of a complete cardiac device ecosystem in Australia encompassing research, clinical trials, commercialization and the development of new manufacturing capabilities," Prof Gregory said. "It is expected to reduce the numbers of deaths by heart failure while improving their longevity and quality of life."

MACH7 TECHNOLOGIES

Mach7 says New York's Docpanel has renewed its Enterprise imaging platform and Eunity diagnostic viewer agreement for \$1.9 million over three years.

Mach7 said Docpanel was "the largest radiology marketplace connecting imaging providers and patients to a network of over 600 US-based academic and subspecialty radiologists ... [and] "with coverage across every state, specialty and modality, Docpanel addresses radiology resource shortages by connecting clients to a network of remote fellowship-trained subspeciality radiologists".

The company said the three-year subscription licence had a minimum fixed fee, a total minimum value of \$1,900,000 and would generate annual recurring revenue of about \$600,000; with the renewal worth a further \$500,000 in annual recurring revenue based on minimum volumes compared to the previous contract and was effective from April 1, 2024. Mach 7 said the contract "offered further upside should volume continue to exceed current contract minimums".

Mach7 managing-director Mike Lampron said it was "the largest renewal program in Mach7's history and creates a foundational book of business for the medium term". "Our focus on building lasting relationships was reflected in our strong customer retention and the [total contract value] increase achieved across this install base illustrates the success of our 'land and expand strategy' which will provide further upside into the future," Mr Lampron said. "The Docpanel renewal also highlights our ability to provide solutions in an agnostic nature to the three biggest public cloud providers in [Amazon web services], Microsoft Azure and Google".

"Looking ahead to 2025, the focus will be on net new logos as our pipeline continues to grow and reflects opportunities across multiple geographies and product combinations," Mr Lampron said.

Mach7 was unchanged at 67 cents.

ADHERIUM

Adherium says it will provide its Hailie Smartinhaler for respiratory and asthma management to the Atlanta, Georgia-based Modivcare's Value Relationships Inc. Adherium said Value Relationships Inc was a personalized healthcare service owned by Modivcare and had more than "2.5 million annual person-to-person interactions in the US and active monitoring of over 155,000 members".

The company said the collaboration would "transform the management of chronic respiratory conditions such as asthma and chronic obstructive pulmonary disease" by integrating its pioneering Hailie technology into Value Relationship's protocols. Adherium said it had signed a supply agreement and had begun work on a technology integration with the first patients expected to begin using Hailie in August. The company did not disclose the commercial terms of the agreement. Adherium chief executive officer Dr Paul Mastoridis said the partnership was "a testament to Adherium's commitment to harnessing innovative technology to enhance member

Adherium was up 0.2 cents or 11.8 percent to 1.9 cents with three million shares traded.

BIOTRON

care".

Biotron says its 20-partial immune patient, phase II study of 200mg BIT225 for HIV shows it was "safe and generally well tolerated" and met its primary endpoints.

In 2021, Biotron said it had begun a 27-patient, Thailand phase II trial and a 20-patient, Sydney phase II trial of BIT225 in HIV-1-positive populations; and later, said it had completed recruited for the Australian trial (BD: Nov 1, 2021, Oct 4, 2022).

Today, Biotron said the open-label trial was designed to characterize the effect of 200mg BIT225 dosed once daily with standard-of-care anti-retroviral therapy for 12 weeks in previously treated patients who had partial immune reconstitution.

The company said the primary objectives of the trial were to evaluate the safety of BIT225 and determine the impact of the addition of BIT225 to standard-of-care on immune activation, inflammation and viral markers.

Biotron said that preliminary analysis showed "all participants maintained viral suppression throughout the study ... [and] statistically significant differences in the change from baseline were observed during the BIT225 treatment period for several prespecified immune markers and cell populations" (p < 0.05).

The company said baseline values of the immune markers and cell populations were determined in an initial four-week observation period and values were assessed during the 12-week treatment period and a four-week follow-up period, with immune markers and cell populations including natural killer cells and T-regulatory cells.

Biotron said adverse events attributed to BIT225 were "of similar incidence, and mild severity, to those previously reported for the drug" with one person withdrawing from the study following the first dose of study drug during the treatment period.

The company said baseline values for a range of immune activation, inflammation and viral assays were determined for each person during an initial four-week observation period and further values of the same markers were assessed during 12-week. Biotron managing-director Dr Michelle Miller said the preliminary trial results extended the "understanding of BIT225 and complements the results from the previous HIV trials". "Viroporin-targeting drugs such as BIT225 uniquely combine immune modulation with antiviral activity and have the potential to address both the immune and viral pathogenesis of numerous viral infections in a clinically-relevant fashion," Dr Miller said.

Biotron was unchanged at 4.8 cents with 27.4 million shares traded.

MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

Melodiol says it is considering "strategic alternatives" for the use of its Mernova properties and has raised \$5 million in convertible notes from Harbour Capital.

In 2018, the then Creso said it had completed the acquisition of the Halifax, Nova Scotia-based medical marijuana producer Mernova Medicinal for \$C200,000 (\$A201,312) and 8,300,000 Creso Canada shares (BD: Jul 27, 2017; Feb 19, 2018).

Today, the company said two independent firms had appraised its Mernova property at between \$10.4 million and \$12 million, and that the valuation validated "the significant investment it has made in this facility over the preceding years".

Melodiol said it was "considering strategic alternatives to utilise the land and building valuation to simplify and improve its balance sheet, including, but not limited to a potential sale leaseback transaction or a new secured loan".

The company said the appraisals were subject to several assumptions and noted that the estimated market value was "based on its continued operation for its intended use as a cannabis production facility".

Melodiol said the review process was intended to "replace the existing secured noteholders with one group to simplify the structure of the company's balance sheet, and to pursue a lower interest rate than the current secured note structures and potentially provide additional working capital above and beyond the refinancing".

The company said it would raise \$5 million in convertible notes from Harbour Capital Opportunities Fund Pty Ltd at an interest rate of seven percent a year to be raised in five tranches of \$1 million each.

Melodiol said the conversion price of the notes would be the lower of a 30 percent discount to the 20-day volume weighted average price immediately prior to the date of each conversion and eight cents.

The company said the funds were for marketing and sales in Canada, Europe and Australia, general working capital, and might be used to repay existing debt. Earlier this year, Melodiol told an ASX query that it considered its financial condition sufficient to warrant it as an ongoing concern, and that it had a track record of raising capital when required (BD: Mar 12, 2024).

Today, the company said it had "undertaken a significant review of the available sources of capital in the currently challenging and volatile capital markets environment".

Melodiol said it believed that it had "clearly identified a pathway to creating value for shareholders via ongoing revenue growth, debt reduction and reducing operating outflows in an effort to achieve a cash flow positive state".

Melodiol managing-director William Lay said the company was "pleased to see the strong appraisal results for Mernova ... [and] the new convertible notes will be a source of capital that assists us in pursuing this objective".

Melodiol fell 2.3 cents or 57.5 percent to 1.7 cents with 20.8 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has received \$2,624,860 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Last year, Recce said it had up-to \$54,947,284 for research and development on its synthetic antibiotics as an Advanced Overseas Finding from the Federal Government's Department of Industry, Innovation and Science (BD: Dec 14, 18, 2024).

Today, Recce said the incentive related to overseas research and development expenditure for the year to June 30, 2023.

Recce was unchanged at 59 cents.

BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt "pending release of an announcement regarding [US Food and Drug Administration]-approval for Sofdra".

Trading will resume on June 21, 2024, or on an earlier announcement.

Botanix last traded at 33.5 cents.

PHARMAUST

Pharmaust has requested a trading halt "pending an announcement by the company to the market regarding a capital raising".

Trading will resume on June 21, 2024, or on an earlier announcement.

Pharmaust last traded at 22.5 cents a share.

HERAMED

Heramed says there are a record 560 active users of its Heracare remote pregnancy monitoring platform, up 8.3 percent from the previous record on July 21, 2022. Heramed said the number of accumulated Heracare platform users had reached 3,553 registered mothers, up 12 percent since March 31, 2024.

The company said the number of users "was expected to continue growing as a number of previously announced agreements and partnerships" were implemented in 2024. Heramed said the recent increase was a result of its US-based channel partner e-Lovu Health, with 345 active users, as well as the Perth-based private clinic Simply Women and Joondalup Obstetrics and Gynaecology Group with a combined 153 active users. Heramed managing-direct5or Anoushka Gungadin said the operating momentum and feedback from customers and health providers was "translating into rapid accumulated user growth on our Heracare platform".

Heramed was up half a cent or 27.8 percent to 2.3 cents with 3.8 million shares traded.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has appointed Sydney's Lucid Health Consulting to advise it on registration and reimbursement for its TRP-8803 intra-venous psilocin psylocibin. In March, the then Exopharm, said it would merge with the Kelowna, British Columbia-based Tryp Therapeutics and develop programs designed to address "neuro-psychiatric disorders through the therapeutic dosing of synthetic psilocybin and [intra-venous] infused psilocin in conjunction with psychotherapy" (BD: Mar 8, 2024).

Today, the company said Lucid Health were providers of expert advice in health economics, pricing and reimbursement, market access and regulatory affairs in Australia". Tryptamine said Lucid Health would help it advance registration and reimbursement for its drugs in Australia, including ongoing engagement with the Therapeutic Goods Administration, from July 1, 2024.

Tryptamine fell 0.1 cents or five percent to 1.9 cents with 1.9 million shares traded.