

Biotech Daily

Tuesday March 29, 2022

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: TELIX UP 10%; ANTISENSE DOWN 7%
- * TESSARA HOPES TO RAISE \$10m FOR REALBRAIN
- * UNSW FOUNDERS SYNBIO 10X \$840k FOR SIX START-UPS
- * AVECHO TPM-CBD GEL 'HIGHLY SIGNIFICANT FOR OA PAIN'
- * TELIX: FDA ORPHAN STATUS FOR TLX66 TRANSPLANT 'CONDITIONING'
- * TELIX: XIEL REPLACES CURIUM AS ILLUCCIX UK, IRELAND DISTRIBUTOR
- * LIQUIDATORS SELL PALLA UK, NORWAY; 'NOTHING FOR INVESTORS'
- * NYRADA: 'ORAL NYR-BI02 BEATS BI01 FOR BRAIN INJURY, IN MICE'
- * ARTRYA OPENS LOS ANGELES OFFICE
- * DIMERIX RECEIVES \$3.7m FEDERAL R&D TAX INCENTIVE
- * CREDIT SUISSE TAKES 5% OF MESOBLAST
- * RESPIRI APPOINTS EAS US CORPORATE ADVISER

MARKET REPORT

The Australian stock market was up 0.7 percent on Tuesday March 29, 2022, with the ASX200 up 51.9 points to 7,464.3 points. Twenty of the Biotech Daily Top 40 stocks were up, 10 fell and 10 traded unchanged. All three Big Caps were up.

Telix was the best, up 41 cents or 9.9 percent to \$4.56, with 2.3 million shares traded. Polynovo climbed 6.6 percent; Alcidion, Micro-X and Opthea were up five percent or more; Resmed improved 4.1 percent; Avita, Prescient, Pro Medicus and Volpara were up three percent or more; Clinuvel, Kazia, Mesoblast, Nanosonics, Oncosil, Starpharma and Uscom rose more than two percent; Actinogen, Cochlear, CSL, Cynata and Orthocell were up more than one percent; with Medical Developments up 0.5 percent.

Antisense led the falls, down one cent or 7.4 percent to 12.5 cents, with 745,269 shares traded. Immutep, Impedimed and Patrys lost more than three percent; Compumedics shed 2.4 percent; Emvision, Genetic Signatures, Neuren and Paradigm were down more than one percent; with Cyclopharm down 0.3 percent.

TESSARA THERAPEUTICS

Tessara says it has begun a \$10 million capital raise at an undisclosed price for its Realbrain technology for drug development and prepare for pre-clinical studies. Tessara said that the funds would allow it to develop new disease models and bio-material as well as invest in the expansion of its "team of experts".

In May 2020, the company said it had raised \$2.7 million in a "significantly oversubscribed" placement to develop its Realbrain three-dimensional brain tissue technology for drug screening (BD: May 6, 2020).

Today, Tessara said that its Realbrain technology aimed to "employ robotic automation to combine human neural stem cells with proprietary biomaterials in [three-dimensional] micro-environment that induces high-fidelity, natural development of human neural tissue". The company said it had shared the platform for evaluation by drug discovery companies and potential partners and aimed for a commercial rollout "within the next 18 months". Tessara chief executive officer Dr Christos Papadimitriou told Biotech Daily that interested investors should contact him at: christos.p@tessaratx.com.

Tessara is a private company.

UNIVERSITY OF NEW SOUTH WALES FOUNDERS

The University of New South Wales Founders says it has launched the Synbio 10x accelerator program for start-ups in synthetic biology and biotechnology.

The University of New South Wales Founders (UNSW Founders) said that Synbio 10x, would be run with the RNA Institute and the University's School of Biotechnology & Biomolecular Sciences as a national program to provide startups with access to capital, scientific infrastructure and networks to accelerate product development and commercialization.

The UNSW Founders said that 15 teams would be shortlisted for a due diligence phase and six would be selected for full-time access to labs in the University of New South Wales \$250 million biotechnology facility from late June 2022.

The UNSW Founders said that the Commonwealth Scientific and Industrial Research Organisation founded Main Sequence fund would invest \$120,000 into each startup accepted into the accelerator program, with the potential for further investment post program and it would invest a further \$20,000 each into the six successful startups. The organization said that Synbio 10x would be run in two phases, with a pre-accelerator and accelerator program.

University of New South Wales director of entrepreneurship David Burt that "the biggest bottleneck for Australian [synthetic biology] startups is a lack of access to the labs and scientific infrastructure that they need to do product development".

"Lab infrastructure is rare and expensive and so UNSW will give six of the best Australia [synthetic biology] startups six months of free access to everything they need to go fast," Mr Burt said.

Main Sequence principal Gabrielle Munzer said that engineering in biology was "still largely an untapped space".

"But it has the potential to reimagine the way we create food, address climate change, find better health outcomes, and beyond," Ms Munzer said.

Applications close on May 15, 2022.

To apply, go to: <u>https://unswfounders.com/synbio10x-accelerator</u>.

UNSW Founders said that since inception in 2018, its accelerator programs had raised about \$70 million of investment capital post program and generated more than \$250 million in enterprise value.

AVECHO BIOTECHNOLOGY (FORMERLY PHOSPHAGENICS)

Avecho says a 15-patient, phase IIa study shows that tocopheryl phosphate mixturemarijuana-derived cannabidiol shows a "highly significant" osteoarthritis pain reduction. Earlier this month, Avecho said it had begun dosing patients in the study of its tocopheryl phosphate mixture (TPM)-enhanced topical cannabidiol (CBD) gel for (BD: Mar 1, 2022). Today, the company said the single-centre, proof-of-concept study conducted with the Sydney-based Lambert Initiative included a week of baseline measurements, four weeks of daily treatment of the affected joints of a single hand and a week of washout. Avecho said the trial showed a "highly significant" (p < 0.001) reduction in pain and increase in grip strength (p < 0.001) and functionality compared to baseline. The company said that "most participants" also saw "statistically significant" (p < 0.001)

The company said that "most participants" also saw "statistically significant" (p < 0.00" decreases in self-reported stiffness of fingers and anxiety.

Avecho chief executive officer Dr Paul Gavin said that "we have already received commercial interest in a topical CBD formulation and are confident that data from this study will be of interest to potential licencees".

The company said it would plan larger, placebo-controlled studies in collaboration with the Lambert Initiative and that the results of this study would be released in June 2022. In 2009, the then Phosphagenics said that in a 12-patient phase Ib trial for inflammatory pain, TPM-diclofenac showed more rapid absorption and deeper penetration than Voltaren (diclofenac) alone and TPM increased absorption by 380 percent (BD: Sep 10, 2009). Avecho was up 0.1 cents or 7.7 percent to 1.4 cents with 3.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says that the US Food and Drug Administration has granted TLX66 orphan drug designation for conditioning treatment prior to haematopoietic stem cell transplant. The company said that prior to haematopoietic stem cell transplant, bone marrow "conditioning" cleared a patient's bone marrow of cells, replaced by stem cells to encourage production of new bone marrow that produced healthy blood cells. Telix said traditional conditioning methods were "associated with morbidity and mortality from chemotherapy, limiting their use particularly in paediatric and rare diseases". The company said that TLX66 (90-yttrium-besilesomab) had the "potential to add to the depth of conditioning, thereby removing additional disease-causing cells ... [and its] potential to reduce the toxicity of existing conditioning regimens could increase the number of patients that are eligible for transplant".

Telix said that orphan designation qualified TLX66 for drug development incentives, which might include seven years market exclusivity, waived FDA fees and tax incentives. In May 2021, The company said that a nine-patient, phase I/IIa trial of TLX66 for systemic amyloid light chain amyloidosis met its study objectives of safety (BD: May 25, 2021). Today, Telix chief medical officer Dr Colin Hayward said that "the granting of an orphan drug designation by the FDA for TLX66, combined with recent encouraging data from prior studies in haematological malignancies and autoimmune disease provides a strong impetus to advance our development plans for TLX66".

"This treatment has potential application in a number of haematological cancers and rare diseases and potentially also in the future for conditioning for cell and gene therapies," Dr Hayward said.

Telix said that TLX66 had previously been granted orphan drug designation status by the European Medicines Agency in Europe for treatment in haematopoietic stem cell transplantation.

Telix was up 41 cents or 9.9 percent to \$4.56 with 2.3 million shares traded.

TELIX PHARMACEUTICALS

Telix says that Xiel will replace Curium as its distributer of its Illuccix prostate cancer imaging product in the UK and Republic of Ireland, effective from May 1, 2022. Telix said Illucix was the kit for the preparation of 68-gallium prostate specific membrane

antigen-11 (68Ga-PSMA-11) and that the Shepton Mallet, Somerset-based Xiel would be its exclusive distributor for three years from the national approval date.

Xiel managing-director Jack Knight said that PSMA positron emission tomography imaging was "emerging as the standard of care having recently been included in European and US clinical practice guidelines".

"This commercial partnership with Telix will enable us to open the door to state-of-the-art PSMA imaging for the 61,000 men diagnosed with prostate cancer each year in the UK and the Republic of Ireland," Mr Knight said.

Telix Europe Middle East and Africa chief executive officer Richard Valeix said the UK and Ireland were "one of Telix's largest potential markets within the … region, so we are pleased to have secured this agreement in anticipation of regulatory approval".

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES ENTERPRISES)

Korda Mentha's Craig Shepard and Bryan Webster as liquidators of Palla Pharma said they have sold Palla Pharma UK and Palla Pharma Norway Holdings AS.

The liquidators did not disclose the amount received but said that the UK entity was sold on March 19 and the Norway entity was sold on March 28, 2022.

The liquidator said that "in line with our administrators report, dated March 2, 2022, we advise that we do not expect there will be sufficient recoveries available in the liquidation to provide a return to shareholders".

Palla Pharma was suspended and last traded at 29.5 cents.

<u>NYRADA</u>

Nyrada says that its lead brain injury drug candidate NYR-BI02 showed "excellent oral bioavailability" in pre-clinical studies and will advance in its phase I first-in-human study. Nyrada said that exploratory pharmacokinetic studies indicated that NYR-BI02 had the potential to be administered orally to patients who suffer a concussion, where intravenous infusion is not preferred.

Nyrada chief executive officer James Bonnar told Biotech Daily the work was in mice. The company said that NYR-BI02 was an improved modification of NYR-BI01, which it had previously selected for traumatic brain injury studies (BD: Jun 15, 2021). Today, Nyrada said that an oral dose that could be administered immediately after an

injury, without waiting for hospitalization with the potential to improve patient outcomes. Nyrada was up 1.5 cents or 7.7 percent to 21 cents.

<u>ARTRYA</u>

Artrya says its American subsidiary, Artrya USA Inc. has opened its US headquarters in Los Angeles, California.

Artrya said that its main product was the Salix Coronary Anatomy, an artificial intelligencebased technology "capable of analyzing cardiac [computerized tomography] scans to illustrate a unique combination of coronary artery disease biomarkers, including components of high-risk plaque".

Artrya was up three cents or 2.9 percent to \$1.08.

<u>DIMERIX</u>

Dimerix says it has received \$3,695,563 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.

Dimerix said the rebate related to research and development expenditure for the year to June 30, 2021.

Dimerix was unchanged at 17.5 cents.

MESOBLAST

The Sydney-based Credit Suisse Holdings says it has become a substantial holder in Mesoblast with 32,871,412 shares or 5.05 percent.

Credit Suisse said it bought, borrowed, returned and transferred shares under an Overseas Securities Lenders' Agreement and the Australian Securities Lending Agreement between November 25, 2021 and March 24, 2022, with the single largest purchase on November 30, 2021 of 99,833 shares for \$169,733 or \$1.70 a share. Mesoblast was up 2.5 cents or 2.2 percent to \$1.14 with one million shares traded.

<u>RESPIRI</u>

Respiri says it has appointed New York's EAS Advisors LLC as its US corporate adviser to "assist with US growth" for its Wheezo asthma monitor.

Respiri said that EAS provided companies with "access to local industry contacts to enhance their growth and expansion".

Respiri was up 0.1 cents or 1.8 percent to 5.7 cents with 1.55 million shares traded.