# Biotech Daily

Tuesday February 16, 2021

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: PROTEOMICS UP 19%; USCOM DOWN 6%**

*** PRO MEDICUS: $31m, 7-YEAR UNIVERSITY OF CALIFORNIA HEALTH DEAL**

*** CZECH APPROVAL '1st NATIONAL APPROVAL FOR TELIX TLX591-CDX'**

*** TALI RAISES $3.85m**

*** RECCE 'READY FOR SPRAY-ON R327 BURNS INFECTION TRIAL'**

*** NEUREN ADDS PRADER-WILLI SYNDROME TO NNZ-2591 PIPELINE**

*** AROA: MYRIAD 'REDUCES SURGICAL COMPLICATIONS'**

*** VIVAZOME, LA TROBE UNI EXOSOMES COLLABORATION**

*** CLARITY ACQUIRES MELBOURNE UNI PATENT PORTFOLIO**

*** INCANNEX MOUSE TRIAL TAKES IHL-675A TO IBD**

*** ZELIRA ENDS SUDA FEASIBILITY STUDY**

*** CANN REQUESTS 'FEDERAL COURT NOTICE APPLICATION' HALT; CORRECTION**

*** REGAL REDUCES TO 9% OF ALTERITY**

*** JIMMY THOMAS, IVY PONNIAH TAKE 7.6% OF LIVING CELL**

*** INVEX APPOINTS OPTHEA'S DR MEGAN BALDWIN DIRECTOR**

## MARKET REPORT

The Australian stock market was up 0.7 percent on Tuesday February 16, 2021, with the ASX200 up 48.4 points to 6,917.3 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell and five traded unchanged. All three Big Caps were up.

Proteomics was the best, up 17 cents or 19.3 percent to $1.05, with 964,817 shares traded. Optiscan climbed 10.3 percent; Imugene improved 9.5 percent; Starpharma was up 8.7 percent; Resonance rose 5.6 percent; Orthocell was up 4.55 percent; CSL and LBT were up more than two percent; Compumedics, Medical Developments and Opthea were up more than one percent; with Avita, Cochlear, Paradigm, Resmed and Telix up by less than one percent.

Uscom led the falls, down one cent or 5.9 percent to 16 cents, with 148,769 shares traded. Alterity, Oncosil, Osprey, Prescient and Volpara fell four percent or more; Amplia, Dimerix, Impedimed, Patrys and Pharmaxis lost more than three percent; Antisense, Cynata, Kazia, Nanosonics, Nova Eye and Pro Medicus shed two percent or more; Clinuvel and Immutep were down more than one percent; with Cyclopharm, Mesoblast and Polynovo down by less than one percent.

## PRO MEDICUS

Pro Medicus says its US subsidiary Visage Imaging has signed a $31 million, seven-year contract with five University of California health systems.

Pro Medicus said Visage had signed the deal with the University of California health systems at Los Angeles (UCLA), San Francisco (UCSF), San Diego (UCSD), Davis (UCD) and Irvine (UCI).

The company said that planning for the system rollout to replace multiple legacy picture archive communication systems, “unifying all five academic campuses on a single … imaging platform” would start immediately with installation targeted for this year.

Pro Medicus chief executive officer Dr Sam Hupert said the contract was “a highly sought after, extremely competitive tender and as you would expect for such a large and highly sophisticated client, they underwent a very extensive evaluation process that included onsite [pilot programs] involving all five main campuses”.

“We have won six out of six of the major contracts in our market over the last seven months,” Dr Hupert said. “These have been across a broad range of opportunities in both the academic and non-academic-[integrated delivery network] space, five in North America and one in Europe.”

Dr Hupert said the contracts confirmed that the Pro Medicus products were “more so than any other, is ideally suited to a large percentage of the total addressable market”.

Pro Medicus fell $1.37 or 2.9 percent to $45.65 with 308,889 shares traded.

## TELIX PHARMACEUTICALS

Telix says Czech Republic’s Ministry of Health approval of TLX591-CDx for prostate cancer imaging using positron emission tomography is its first national approval.

Last year, Telix said the US Food and Drug Administration had approved the institutional use of 68 Gallium-prostate specific membrane antigen-11 (68Ga-PSMA-11) for prostate cancer imaging at the University of California (BD: Dec 2, 2020).

Today, the company said its TLX591-CDx kit would be used by Czech physicians to prepare 68Ga-PSMA-11 under a specific therapeutic program .

Telix said the program allowed “medical products intended for the treatment, prevention or diagnosis of conditions severely affecting human health to be used prior to being granted a full European marketing authorization” and was valid until December 31, 2022.

The company said that under the program its diagnostic imaging of prostate cancer would use positron emission tomography with computed tomography (PET/CT) or magnetic resonance imaging (PET/MRI)

Telix said the diagnostic would be used for primary staging of high-risk disease for early identification of metastases; localization of prostate cancer in patients with prostate specific antigen progression following radical treatment; and identification of patients with extensive generalized prostate cancer where radical treatment was not indicated.

Czech Society of Nuclear Medicine president Dr David Zogala said the Society considered the “temporary approval of PSMA PET in the Czech Republic to be a very important milestone, with an immense impact on the quality of prostate cancer care”.

“Accessibility to this valuable examination would increase across the Czech Republic, as previously it was limited to one single pioneer hospital in Pilsen,” Dr Zogala said.

Telix chief executive officer Dr Christian Behrenbruch said “the Czech Republic was the first European country to grant broad patient access to PSMA imaging and we look forward to working with … [distributor] THP Medical to ensure this state-of-the-art imaging modality is available to all men in the Czech Republic living with prostate cancer".

Telix was up three cents or 0.7 percent to $4.15 with 384,700 shares traded.

## TALI DIGITAL

Tali says it has raised $3.85 million in a placement at 3.9 cents a share to institutions and sophisticated investors.
Tali said it would use the funds to accelerate licencing agreements in the US and Japan, partnerships in India, and domestic commercialization of its Detect and Train products.
The company said Taylor Collison was the sole lead manager on the placement and, pending shareholder approval, would be offered 15 million options exercisable from nine cents to 15 cents each within 18 months to 24 months after completion of the placement.
Tali was up 0.1 cents or 2.4 percent to 4.3 cents.

## RECCE PHARMACEUTICALS

Recce says it will start a 30-patient, phase I/II clinical trial of R327 for topical burn wound infections by April 2021 at Perth's Fiona Stanley Hospital burns unit.
Last October, Recce said 10 patients would receive R327 daily for 14 days with 20 patients receiving R327 three times a week (BD: Oct 16, 2020).
Today, the company said the study would assess the safety and efficacy of a spray-on formulation of its broad-spectrum synthetic antibiotic R327 for patients with gram-positive and gram-negative bacterial burn wound infections.
Recce said the trial would be led by Royal Perth and Fiona Stanley Hospital's clinical microbiologist and infectious diseases expert Dr Edward Raby, Fiona Stanley hospital's head of infectious diseases Dr Chris Health and the State Adult Burns Unit director Prof Fiona Wood.
Last year, Recce said Adelaide's CMax Clinical Research facility would conduct its 48-patient phase I trial of Recce-327 for blood infection and sepsis (BD: Sep 10, 2020)
Today, the company said the two studies would "run in parallel demonstrating the broad administration capabilities of R327".
Recce fell two cents or 1.8 percent to $1.09.

## NEUREN PHARMACEUTICALS

Neuren says that "compelling results" from a mouse study has led it to add Prader-Willi syndrome to its developmental pipeline for NNZ-2591.
Yesterday, Neuren said its 16-volunteer, phase I trial of NNZ-2591 showed that twice daily oral dosing for seven-day was "safe and well tolerated" (BD: Feb 15, 2021).
Today, the company said the blinded, controlled pre-clinical study showed "compelling effects of treatment on key symptoms" after treatment with NNZ-2591 in a Magel2-null mouse model of Prader-Willi syndrome.
Neuren said it would submit US and EU orphan drug applications and begin phase II development for Prader-Willi syndrome, a disease; "characterized by insatiable hunger, obesity, diabetes, weak muscles, intellectual disabilities and behavioral problems".
The company said the two dose levels normalized behavioral deficits, with the high dose eliminating obesity and reducing abnormally high insulin levels to normal, as well as increasing abnormally low levels of insulin like growth factor (IGF-1) to normal.
The company said low dosage of NNZ-2591 partially improved obesity, insulin levels and the circulating IGF-1 levels.
Neuren chief executive officer Jon Pilcher said the results "once again reinforced the potential for NNZ-2591 to make a difference across multiple neuro-developmental disorders in which signalling between brain cells and IGF-1 metabolism are impaired".
Neuren was unchanged at $1.40.

## AROA BIOSURGERY

Aroa says a pilot study showing its sheep stomach-based Myriad for soft tissue reconstruction can be used to reduce surgical complications in chronic wounds.

Aroa said the study, titled 'Case Report: Surgical Closure of Chronic Soft Tissue Defects Using Extracellular Matrix Graft Augmented Tissue Flaps', was published in the journal Frontiers of Surgery and the full text was available at https://www.frontiersin.org/articles/10.3389/fsurg.2020.559450/full.

The company said the pilot study involved the reconstruction of nine non-healing wounds at the Phoenix, Arizona-based Abrazo Arrowhead Hospital and included pressure injuries and surgical wounds by using the Myriad device as an implant under a soft tissue flap.

Aroa said that "only one minor surgical complication was observed, and all wounds went on to fully heal, even when Myriad was used in a contaminated field".

"By contrast, a retrospective review of the flap reconstruction of chronic pressure injuries reported a complication rate of 58 percent," the company said.

Aroa chief executive officer Brian Ward said the study supported the clinical evidence for the efficacy of Myriad.

"This latest study showing the potential benefits of Myriad in flap reconstruction of chronic wounds builds on two other clinical studies published since November last year showing the efficacy of Myriad in the surgical treatment of serious cases of the inflammatory skin condition hidradenitis suppurativa and when patients underwent surgical reconstruction to achieve coverage over exposed vital structures such as bone and tendon," Mr Ward said.

Aroa fell 3.5 cents or 2.9 percent to $1.18.

## VIVAZOME THERAPEUTICS PTY LTD

Vivazome says it has a research collaboration with Melbourne's La Trobe University to develop exosome therapeutics for ischaemia, fibrotic diseases and neurological disorders.

Vivazome said that the partnership La Trobe University focussed on developing new exosome therapeutics with members of Prof Andrew Hill's laboratory at the La Trobe Institute for Molecular Science.

The company said that Prof Hill was "one of the world's pre-eminent exosome researchers and a member of the La Trobe Research Centre for Extracellular Vesicles, with its extensive suite of specialized technology and high-level expertise".

Vivazome said the agreement built on work done by Vivazome and La Trobe as part of the successfully completed co-operative research centre project (CRC-P), titled 'Enabling Exosome Therapy: Developing an Advanced Manufacturing Process'.

The company said that La Trobe University "played a key role in the project through development of functional assays and the quantitative and qualitative assessment of exosome fractions from multiple cell types and multiple process iterations".

Vivazome said that the University's ability for analysis of micro-RNA (miRNA) content enabled it to link exosome content to biological activity and potential clinical application.

Vivazome chief executive officer Dr David Haylock told Biotech Daily the company expected to manufacture materials for pre-clinical trials in Australia by the end of this year.

In a media release Dr Haylock said that as the company "broadens its portfolio of activity to … ischaemia, fibrotic diseases and neurological disorders, La Trobe's world-class capability will provide a strong analytical platform for the development of [our] products".

La Trobe pro vice-chancellor of industry engagement Dr Megan Fisher said the University was "committed to making a difference to industry".

Vivazome is a private company.

## CLARITY PHARMACEUTICALS

Clarity says it has completed the assignment of its underlying patent portfolio from the University of Melbourne, providing full rights and ownership of the patents.

Clarity said it previously held exclusive licences on several granted patents and patent applications from the University of Melbourne relating to its radio-pharmaceutical technology for diagnostic and therapeutic for cancers, in particular the Sarcophagene chelators for use with copper-64 and copper-67.

Clarity executive chair Dr Alan Taylor told Biotech Daily that the portfolio included multiple patent families.

In a media release Dr Taylor said the University was “one of the main collaborating institutions … on many levels, including basic research, early pre-clinical development, intellectual property, grant funding and direct investment”.

“The research of Prof Paul Donnelly and his team at the School of Chemistry and Bio21 Institute of Molecular Science and Biotechnology, University of Melbourne, has been critical to the successful development and commercialization of Clarity’s platform … technology,” Dr Taylor said.

The company said that its lead products in development were Sartate, Sar-bisPSMA and Sar-Bombesin.

Clarity is a public unlisted company.

## INCANNEX HEALTHCARE

Incannex says its begun its fifth program for its marijuana based IHL-675A to assess its anti-inflammatory capability to treat inflammatory bowel disease.

Incannex said that a previous mouse study showed that the combined cannabidiol and hydroxychloroquine IHL-675A had “superior anti-inflammatory activity” compared to cannabidiol or hydroxychloroquine in a mouse model of colitis, which was a form of inflammatory bowel disease.

The company said its target indications for IHL-675A included sepsis-associated acute respiratory distress syndrome, chronic obstructive pulmonary disease, asthma and bronchitis.

Incannex was up four cents or 18.2 percent to 26 cents with 42.4 million shares traded.

## SUDA PHARMACEUTICALS, ZELIRA (FORMERLY ZELDA) THERAPEUTICS

Suda and Zelira say they will cease their work on an oral marijuana spray and not progress from a feasibility study to a development and licencing agreement.

In 2018, the then Zelda said it had partnered with Suda to conduct a feasibility to develop an oral spray delivery system for its marijuana cannabinoid derivatives, using Suda’s Oromist oro-mucosal spray (BD: Dec 6, 2018).

In 2019, Suda said it had a $1.5 million deal to develop its Oromist spray for marijuana derivatives with Canberra’s Cann Pharmaceutical Australia (BD: Oct 30, 2019).

Today, the company said it would continue its focus on its partnership with Cann Pharma Australia and on existing partnerships for its other products.

Suda was up 0.1 cents or 2.1 percent to 4.8 cents with 3.4 million shares traded.

Zelira fell 0.2 cents or 2.4 percent to eight cents with 4.3 million shares traded.

## CANN GROUP

Cann has requested a trading halt pending “an application to the Federal Court … seeking orders in relation to [its] inadvertent failure to lodge a cleansing notice”.
Trading will resume on February 18, 2021 or on an earlier announcement.
Cann last traded at 77.5 cents.

## CORRECTION: CANN GROUP

Last night’s edition correctly reported that Cann Group has bought Satipharm for $C4 million ($A4.06 million), but failed to say it was in Cann Group shares.
The mistake was made by the new Monday sub-editor who was working from home in isolation, during the Melbourne lockdown, which masked the specificity of the deal.
Biotech Daily apologises unreservedly.

## ALTERITY THERAPEUTICS

Regal Funds Management says it has reduced its substantial shareholding in Alterity from 208,853,236 shares (10.28%) to 184,853,236 shares (8.87%).
The Sydney-based Regal Funds said that it sold the 24,000,000 shares on February 11, 2021, for $956,400, or 3.985 cents a share.
Alterity fell 0.2 cents or 4.4 percent to 4.3 cents with 17.6 million shares traded.

## LIVING CELL TECHNOLOGIES

Jimmy Thomas and Ivy Ruth Ponniah say they have increased their substantial holding in Living Cell from 35,573,386 shares (6.23%) to 43,573,386 shares (7.625%).
The Melbourne-based Mr Thomas and Ms Ponniah said that on February 11 and 12, 2021 they bought 8,000,000 shares for $181,994 or an average of 2.27 cents a share.
Living cell was unchanged at 2.2 cents.

## INVEX THERAPEUTICS

Invex says it has appointed Dr Megan Baldwin as an independent non-executive director, effective from today.
Invex said Dr Baldwin was currently Opthea’s managing-director and had more than 20 years’ experience in therapeutic cancer drug development and ophthalmic indications.
The company said that previously Dr Baldwin was a postdoctoral researcher at Genentech (now Roche) and was a deputy chair of Ausbiotech.
Invex said Dr Baldwin held a Bachelor of Science and Doctor of Philosophy from the University of Melbourne.
The company said Dr Baldwin would receive a salary of $50,000 a year and, pending shareholder approval, would be granted 400,000 options exercisable at $1.10 each within three years.
Invex was up seven cents or 7.7 percent to 98 cents.