# Biotech Daily

Monday May 30, 2022

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: UNIVERSAL BIOSENSORS UP 8%; AMPLIA DOWN 8%**

*** SANOFI, CRASH BANG WALLOP HAEMOPHILIAC JOINT SCANNER**

*** TRUSCREEN REVENUE UP 48% TO $1.5m, LOSS UP 126% TO $7.2m**

*** TELIX: CMS ILLUCCIX 'PASS-THROUGH' REIMBURSEMENT**

*** ACRUX WINS ALMIRALL ACZONE PATENT ACTION**

*** CYNATA: ST GEORGE JOINS COVID-19 TRIAL**

*** INVION: INV043 REDUCES TUMOR SIZE 65%, IN MICE**

*** BIOTRON: FDA BIT-225 COVID-19 GUIDANCE**

*** ZELIRA ENROLS MARIJUANA FOR DIABETIC NERVE PAIN PATIENTS**

*** CRESO, OPTIMI PSILOCYBIN, MUSHROOMS DEAL**

*** ELLERSTON REDUCES TO 7.5% IN ATOMO**

*** VIBURNUM TAKES 26.5% OF UNIVERSAL BIOSENSORS**

*** PERENNIAL BELOW 5% IN IMEX**

*** EXOPHARM LOSES 2 STAFF, PAY CUTS, BELT-TIGHTENING**

*** PARADIGM APPOINTS MARCO POLIZZI CEO, DR DONNA SKERRETT CMO**

*** MEDICAL DEVELOPMENTS APPOINTS TARA EATON CO SEC, COUNSEL**

*** ADHERIUM APPOINTS TARA CREAVEN-CAPASSO; CFO**

*** PHARMAUST: FIONA MILNER EPICHEM G-M, INGRID KLOPPER BDM**

## MARKET REPORT

The Australian stock market was up 1.45 percent on Monday May 30, 2022, with the ASX200 up 103.9 points to 7,286.6 points. Twenty-five of the Biotech Daily Top 40 stocks were up, six fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Universal Biosensors was the best, up 3.5 cents or 7.95 percent to 47.5 cents, with 425,582 shares traded, followed by Telix up 7.94 percent to $4.62, with 1.1 million shares traded. Avita rose 7.2 percent; Clinuvel, Neuren, Polynovo and Prescient climbed more than six percent; Amplia and Nanosonics improved five percent or more; Cyclopharm was up four percent; Immutep, Medical Developments, Next Science, Paradigm, Pharmaxis, Pro Medicus and Proteomics were up more than three percent; Cochlear, Compumedics, Emvision, Impedimed, Imugene, Kazia, Opthea and Resmed rose more than two percent; with CSL, Orthocell and Volpara up by more than one percent.

Amplia led the falls, down one cent or 8.3 percent to 11 cents, with 919,176 shares traded. Dimerix lost 6.45 percent; Micro-X and Resonance retreated more than two percent; Oncosil was down more than one percent; with Genetic Signatures down by 0.8 percent.

## SANOFI SA, CRASH BANG WALLOP

The Paris-based Sanofi says that an Australian-designed, first-of-its-kind 'augmented reality' technology will be used to monitor joint disease in haemophiliacs.

Sanofi said the technology was designed by Melbourne's Crash Bang Wallop and the first use has been at Sydney's Children's Hospital at Westmead.

The company said that the technology enabled young people with haemophilia "to view the potentially irreversible impact of disabling joint disease".

Sanofi said that haemophilia was an incurable, inherited rare blood disorder affecting more than 3,000 Australians and diagnosed when there was not enough clotting factor VIII or IX in the blood, with bleeding most common in the joints of the knees, elbows and ankles, which could lead to joint disease if not treated adequately.

The company said that the augmented reality joint scanner would be used by clinical staff to "help educate young patients and their families on the possible future impact of joint disease and the importance of maintaining a regular treatment program to help prevent bleeding episodes".

Sanofi said the scanner used a 'leap motion' three-dimensional camera attached to a computer to scan and map a person's hand when placed under the device.

The company said that software overlaid imagery onto the user's hand to replicate normal ageing and the impact of joint disease.

Sanofi said that the scanner of the hand was a reference point "to see what is happening elsewhere in the body, focusing on specific joints known to be impacted by haemophilia including the shoulder, knee, or ankle".

Crash Bang Wallop joint scanner developer Murray White said that "technological advances like augmented reality, seen in this joint scanner, allow healthcare professionals to bring important health education to life that directly engages their patients".

"We know improved health education can help patients make informed decisions about managing their health conditions," Mr White said.

Sanofi said that the joint scanner would be "provided on loan to hospitals across Australia … as an educational resource for patients and their families".

Crash Bang Wallop is a private company.

## TRUSCREEN

Truscreen says revenue for the year to March 31, 2022 rose 48.2 percent to $NZ1,678,465 ($A1,531,337) with net loss after tax up 126.15 percent to $NZ7,892,672 ($A7,198,832).

Truscreen said sales came primarily from its cervical cancer test, with China a main contributor, but said that Covid-19 continued to be an inhibiting factor in all countries, with sales in Vietnam and Eastern Europe deferred, and in Russia compounded by the recent war in Ukraine.

Last week, the company said it would "book a provision for impairment of the remaining carrying value of the non-current assets in the amount of [about] $NZ4.6 million" due to "geopolitical tensions in Ukraine, the impact of China's zero Covid-19 policy with the Chinese borders remaining closed, prolonged Covid-19 lockdowns in other markets, rising inflation and interest rates and disruption to international supply chains".

Truscreen said diluted loss per share was up 101.85 percent, from 1.08 NZ cents at March 31, 2021 to 2.18 NZ cents at March 31, 2022, with net tangible assets per share down 46.0 percent to 0.94 NZ cents, and it had cash and cash equivalents of $NZ2,797,004 at March 31, 2022 compared to $NZ5,255,074 at March 31, 2021.

Truscreen fell 0.3 cents or 5.6 percent to 5.1 cents.

## TELIX PHARMACEUTICALS

Telix says the US Centers for Medicare and Medicaid Services (CMS) has granted transitional pass-through payment status for its Illuccix prostate cancer imaging agent.

Telix said that from July 1, 2022, the transitional pass-through payment status would enable the CMS to "provide separate payments for the radio-pharmaceutical and the [positron emission tomography (PET) - computed tomography (CT)] scan, when performed with Illuccix in the hospital outpatient setting".

The company said from that date, the CMS and commercial health insurers would recognize the healthcare common procedure coding system level II code, A9596 assigned to Illucix, or the kit for the preparation of 68-gallium prostate specific membrane antigen-11 (68Ga-PSMA-11), for reimbursement.

Telix said that Illucix could be ordered by health care professionals from 128 pharmacies and was accessible to about 85 percent of positron emission tomography imaging sites across the US, with more to be added "in the coming months".

Telix chief executive officer Dr Christian Behrenbruch said that "Illuccix is fulfilling an unmet need for convenient and flexible access to PSMA-PET imaging for patients across the country".

"This diagnostic agent is being rapidly adopted by physicians, who recognize its value in determining the extent of disease and to guide treatment decisions," Dr Behrenbruch said.

"With prostate cancer the most common cancer in American men, after skin cancer, this reimbursement milestone is a win for patients and will facilitate even greater access to this tool which is quickly being considered as a potential standard of care," Dr Behrenbruch said.

Telix was up 34 cents or 7.9 percent to $4.62 with 1.1 million shares traded.

## ACRUX

Acrux says the patent litigation in the US District Court of New Jersey with Almirall LLC over a generic version of Almirall's Aczone gel has "concluded in its favor".

Last year, Acrux said the Exton, Pennsylvania-based Almirall began litigation, challenging an Acrux regulatory application made in April for dapsone gel 7.5 percent, a generic version of Almirall's Aczone gel (BD: Jun 8, 2021).

At that time, the company said that anti-acne gel treatment filing under Paragraph IV of the US Code of Federal Regulation relating to an abbreviated new drug application (ANDA) to the US Food and Drug Administration asserted that the Almirall's patent, 9,517,219 was invalid, unenforceable and/or would not be infringed by Acrux's product

Today, Acrux said that on May 27, 2022, the US District Court of New Jersey "dismissed all claims against Acrux DDS Pty Ltd in the patent litigation between Almirall LLC and Acrux DDS Pty Ltd, after the invalidity of Almirall's US Patent Number 9,517,219 was affirmed by the US Court of Appeals for the Federal Circuit".

The company said that the dismissal cleared "all patent litigation related to Acrux's Paragraph IV certification submitted with its ANDA and will allow [it] to launch its generic equivalent to Aczone gel, 7.5 percent in conjunction with its commercial licensee once the product has completed the regulatory review and approval process with the US FDA".

Acrux managing-director Michael Kotsanis said that the "successful legal decision for Acrux now paves the way for us, on approval, to launch our generic product from a development pipeline of 15".

"New product launches provide additional revenue streams and are a key component of our corporate vision and strategy," Mr Kotsanis said.

Acrux was up 0.9 cents or 13.6 percent to 7.5 cents.

## CYNATA THERAPEUTICS

Cynata says that Sydney's St George Hospital has joined its 'Mend' trial of Cymerus mesenchymal stem cells for 24 adult Covid-19 and respiratory failure patients.

Last year, Cynata said it had enrolled the first of 24-patients for its open-label, randomized, controlled Covid-19 trial (BD: May, 24, 2021).

Today, the company said that the inclusion of St George Hospital, which has around 550 beds, would accelerate the recruitment process.

Cynata chief medical officer Dr Jolanta Airey said that "we passed the half-way point in the trial several months ago but we are also taking additional steps to further increase the pool of potential subjects despite continued challenges faced by the hospital system".

"We expect that the addition of this large teaching hospital will accelerate active participation of trial subjects and provide greater assurance toward timely completion later this year," Dr Airey said.

Cynata was unchanged at 40 cents.

## INVION

Invion says its third proof-of-concept study with Melbourne's Hudson Institute of Medical Research showed that INV043 reduced tumor size 65 percent, in mice.

Invion said that the study with the Monash University-based Hudson Institute was designed to evaluate whether INV043 with Photosoft light therapy could be used in combination with immune checkpoint inhibition targeting the programmed cell death protein-1 (PD-1) to improve outcomes in mice with triple negative breast cancer.

Last year, Invion said that INV043 Photosoft light therapy killed triple negative breast cancer tumors in mice, with a "protective immunity" suggested (BD: Oct 28, 2021).

Today, Invion said that unlike previous proof-of-concept studies, administration was restricted to a small portion of the tumor to "specifically probe the combination approach and immune-mediated changes following therapy in an animal model".

Invion said that the combination of INV043 with anti-PD-1 checkpoint inhibition led to about 65 percent reduction in tumor size in mice treated with the combination therapy, achieved clear tumor stabilization and regression despite the restricted treatment protocol and tumors were "significantly smaller than those in mice that received monotherapy".

The company said that 32 mice in eight groups of four mice in each, with the treatment groups receiving either single therapy anti-PD-1, restricted photodynamic therapy alone, or the combination of both and the control groups receiving either no treatment, INV043 without activation alone, laser alone without INV043 drug, an antibody isotype control, and a photodynamic therapy plus antibody isotype control.

Invion said that it the results were "significant" ($p < 0.05$) but "with such [a] small sample size, the p-value should be considered representative only".

Invion executive chair Thian Chew said the findings "demonstrate the potential of INV043, in combination with immunotherapies like immune checkpoint inhibitors, to both improve patient outcomes and broaden its potential applications".

"Opportunities for strategic collaboration may also provide avenues to develop new combined [intellectual property] and open up additional pathways to commercialize the Photosoft technology," Mr Chew said.

Hudson Institute research group head Dr Andrew Stephens said that "as INV043 induces both direct cell death in the tumor micro-environment as well as the release of tumor neo-antigens, we hypothesized that INV043 would combine with checkpoint inhibition to enhance the anti-tumor efficacy compared to either monotherapy alone".

Invion fell 0.2 cents or 15.4 percent to 1.1 cents with 15.1 million shares traded.

## BIOTRON

Biotron says the US Food and Drug Administration has responded to its pre-investigational new drug application for abti-viral BIT-225 as a treatment for Covid-19.
Biotron said that the response from the Food and Drug Administration (FDA) included an overview of the pre-clinical and clinical development, as well as specific questions relating to regulatory requirements for progressing to filing an investigational new drug application for the Covid-19 indication.
The company said that it sought guidance from the FDA on the design of a proposed phase II clinical trial in recently diagnosed Covid-19 infected individuals and assurance that the pre-clinical data package and manufacturing processes were sufficient to support the next stage of clinical development.
Biotron managing-director Dr Michelle Miller said that “the FDA responses were constructive, highly informative and provide direction in the design of the proposed phase II clinical trial”.
“The recommendations for a small, placebo-controlled, proof-of-concept, dose-finding study, with agreed end points, in line with studies for other respiratory diseases, including influenza, are very welcome,” Dr Miller said.
Biotron fell 1.4 cents or 14.0 percent to 8.6 cents with 23.3 million shares traded.

## ZELIRA (FORMERLY ZELDA) THERAPEUTICS

Zelira says it has completed enrolment of 20-patients in the investigative drug arm of its observational study of its marijuana products for diabetic nerve pain.
In July 2021, Zelira said it had US approval for the study which would evaluate the safety and tolerability of its product compared to an unnamed “multi-billion-dollar big pharmaceutical company drug” (BD: Jul 12, 2021).
The company did not name the drug other than to say it was approved by its institutional review board.
Today, the company said that it expected clinical trial results by the end of this year.
Zelira was up nine cents or 7.4 percent to $1.30.

## CRESO PHARMA

Creso says wholly-owned subsidiary Halucenex Life Sciences has a supply agreement with the Vancouver-based, Optimi Health for psilocybin and mushrooms.
Creso said that Optimi would provide it with European good manufacturing practice-grade psilocybin and functional mushrooms “for health and wellness markets” in the form of whole dried mushrooms, with the initial purchase “free of charge with a $CA1,500 ($A1,646) handling fee to be paid to Optimi”.
The company said it would negotiate with Optimi regarding future purchases once it had completed testing protocols.
Creso was unchanged at 5.3 cents with 2.3 million shares traded.

## ATOMO DIAGNOSTICS

Sydney’s Ellerston Capital and its associates says they have reduced their substantial holdings in Atomo from 49,329,568 shares (8.68%) to 42,736,544 shares (7.49%).
Ellerston said that between December 1, 2021 to May 27, 2022 it bought and sold shares, with the single largest sale 3,591,740 shares for $554,565 or 15.4 cents a share
Atomo was unchanged at eight cents.

## UNIVERSAL BIOSENSORS

Viburnum Funds says it has increased its substantial holding in Universal Biosensors from 27,466,227 shares (15.47%) to 56,077,221 shares (26.47%).
Earlier this month, Universal Biosensors said that the Nedlands, Western Australia-based Viburnum would fully underwrite its $20 million one-for-6.85 entitlement offer, at 77 cents per Chess depositary interest (BD: May 18, 2022).
Today, Viburnum said that between November 1, 2021 to May 27, 2022 it bought shares on market and was allotted 25,893,617 shares on May 27 for $19,938,085 or 77 cents a share pursuant to underwriting the entitlement offer.
Universal Biosensors was up 3.5 cents or 7.95 percent to 47.5 cents.

## IMEX HEALTH SERVICES

The Sydney-based Perennial Value Management says it has ceased its substantial share-holding in Imex.
Perennial said it sold shares between March 25 and May 26, 2022, with the single largest sale 1,000,000 shares for $598,680 or 59.9 cents a share.
Imex was up two cents or 2.9 percent to 71.5 cents.

## EXOPHARM

Exopharm says two executives have left, with non-executive directors and managing-director Dr Ian Dixon cutting their fees and salary by 20 percent to reduce costs.
Exopharm said it was making “some significant changes” including reducing spending on non-core and other areas, pausing salary increasing and limiting international travel costs.
The company said that the non-executive directors had cut their director fees and Dr Dixon had cut his salary by 20 percent.
Exopharm said that chief operating officer Daisy Scarborough and head of finance Dr Johannes Mühl had left the company.
In its Appendix 4C report for the three months to March 31, 2022, Exopharm said it had a cash burn of $3,115,000, mostly on salaries and administration, with cash of $5,648,000.
Exopharm fell 2.5 cents or 13.9 percent to 15.5 cents with 1.5 million shares traded.

## PARADIGM BIOPHARMA

Paradigm says it has appointed Marco Polizzi as its US-based chief executive officer, effective from July 1, 2022.
Paradigm said that Mr Polizzi had more than 30 years of experience in the pharmaceutical industry, working for Mallinckrodt in their generic and branded businesses, at Sandoz in its hospital and specialty markets business and at JHP Pharmaceutical in its generic commercial division.
According to his Linkedin page, Mr Polizzi held a Bachelor of Science and a Bachelor of Marketing from the Springfield-based, Missouri State University and a Master of Business Administration from the St Louis, Missouri Webster University.
The company said that interim chief executive officer Dr Donna Skerrett would continue as its chief medical officer.
Paradigm was up 4.5 cents or 3.7 percent to $1.25 with 821,652 shares traded.

## MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has appointed Tara Eaton as general counsel and company secretary, effective from August 8, 2022.
Medical Developments said Ms Eaton had more than 10 years of experience in the pharmaceutical industry, most recently as general counsel for the Australian Red Cross.
The company said Ms Eaton was the legal and compliance director at Gilead Sciences, legal director at Merck & Co, and as a lawyer with Minter Ellison, and Clayton Utz.
According to her Linkedin page, Ms Eaton held a Bachelor of Arts and Bachelor of Laws from Canberra's Australian National University, and a Master of Laws from the University of Sydney.
Medical Developments said chief financial officer Anita James would act as company secretary until Ms Eaton joined the company.
Medical Developments was up 10 cents or 3.95 percent to $2.63.

## ADHERIUM

Adherium says it has appointed staff member Tara Creaven-Capasso as its Melbourne-based head of quality, regulatory and clinical affairs, from June 2022.
Adherium said that Ms Creaven-Capasso had more than 20 years of experience in the medical device, pharmaceutical, bioscience and vaccine industries, most recently co-founding the Covid-19 Vaccine Corp.
The company said that Ms Creaven-Capasso previously worked for Caduceus Medical Development, Xoma Inc, Elan Pharmaceuticals Inc, Arterial Vascular Engineering Inc, Medtronic Inc, Ista Pharmaceuticals Inc and Bluegrass Vascular Technologies Inc.
According to her Linkedin page, Ms Creaven-Capasso held a Bachelor of Science from the National University of Ireland in Galway.
Adherium said that Robert Spurr's role as interim chief financial officer had concluded and recruiting for the Melbourne-based position was progressing.
Adherium fell 0.1 cents or 10 percent to 0.9 cents.

## PHARMAUST

Pharmaust says it has appointed Fiona Milner as Epichem general manager, from June 29, 2022, with Ingrid Klopper as its business development manager.
Pharmaust said Epichem was its wholly-owned synthetic and medicinal chemistry subsidiary.
The company said that Ms Milner had 25 years of experience in the pharmaceutical industry, most recently as regional sales manager for Novartis Pharmaceuticals and previously at Sanofi Aventis, and held a Bachelor of Science from the University of Western Australia.
Pharmaust said that Ms Klopper had more than 10 years of experience in technical sales and account management, had worked in the life sciences, mining, industrial, agriculture, marine and construction industries, and held a Bachelor of Science from the University of South Africa in Pretoria.
Pharmaust was up 0.3 cents or 3.3 percent to 9.3 cents.