



# Biotech Daily

Wednesday January 27, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: PRESCIENT UP 25%; ANTISENSE DOWN 8.5%**
- \* **CYCLOPHARM \$30m PLACEMENT, SHARE PLAN FOR \$1.5m**
- \* **GENETIC SIGNATURES EASYSscreen STI WINS CE-IVD**
- \* **TELIX DOSES 1<sup>st</sup> US ZIRCON RENAL CANCER IMAGING PATIENTS**
- \* **ADVENTIST HEALTH EXPANDS MACH7 PACS CONTRACT TO \$7.9m**
- \* **AROA Q3 RECEIPTS \$14.9m**
- \* **ELIXINOL RECEIPTS DOWN 57% TO \$14m**
- \* **ATOMO H1 RECEIPTS \$5.8m**
- \* **ANTERIS RECEIPTS DOWN 61% TO \$7.3m**
- \* **USCOM H1 RECEIPTS UP 146% TO 2.7m**
- \* **MEDLAB H1 RECEIPTS DOWN 37% TO \$2.6m**
- \* **IQ3 H1 RECEIPTS DOWN 42.5% TO \$2.5m**
- \* **CELLMID H1 RECEIPTS DOWN 27% TO \$3.5m; \$530k CHINA ORDER**
- \* **PHARMAUST H1 RECEIPTS DOWN 27% TO \$1.3m**
- \* **4D STARTS XV LVAS US PILOT PROGRAM**
- \* **HAPVIDA \$58k, 2-YEAR RENEWAL OF HERAMED HERACARE DEAL**
- \* **IMMUTEP WINS SAFETY APPROVAL FOR IMP321 COVID-19 TRIAL**
- \* **UNIVERSAL BIOSENSORS APPOINTS ENARTIS US SENTIA DISTRIBUTOR**
- \* **EMVISION: FDA ADVISES DE-NOVO PATH FOR BRAIN SCANNER**
- \* **MITSUBISHI SINGAPORE ENDS SUDA ZOLPIMIST LICENCE**
- \* **LITTLE GREEN 2-YEAR FRENCH GOVERNMENT MARIJUANA DEAL**
- \* **NAOS TAKES 27% OF BTC**
- \* **MERCER STREET TAKES 5% OF ANTERIS**
- \* **LIVING CELL TO LOSE CEO DR KEN TAYLOR**
- \* **CSL LOSES 4-MONTH ASTRAZENECA DIRECTOR DR PASCAL SORIOT**
- \* **FACTOR APPOINTS TAYLOR COLLISON ADVISOR**

## MARKET REPORT

The Australian stock market fell 0.65 percent on Wednesday January 27, 2021, with the ASX200 down 44.1 points to 6,780.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell and nine traded unchanged.

Prescient was the best on no news, up 2.4 cents or 25.0 percent to 12 cents, with 26.6 million shares traded.

Cyclopharm and Immutep climbed more than seven percent; Pro Medicus was up 6.4 percent; Starpharma and Universal Biosensors improved more than four percent; Avita, Orthocell and Resmed rose more than two percent; Cochlear was up 1.3 percent; with Clinuvel, Cynata and Nanosonics up by less than one percent.

Antisense led the falls, down two cents or 8.5 percent to 21.5 cents, with 5.3 million shares traded.

Patrys lost 5.7 percent; Impedimed and LBT fell four percent or more; Kazia, Oncosil and Osprey were down more than three percent; Medical Developments, Opthea and Resonance shed two percent or more; Amplia, Dimerix, Genetic Signatures, Neuren, Next Science, Nova Eye, Pharmaxis, Telix and Volpara were down more than one percent; with CSL and Mesoblast down by less than one percent.

## CYCLOPHARM

Cyclopharm says it has commitments to raise \$30.0 million in a placement at \$2.60 a share and hopes to raise \$1.5 million in a share plan.

Cyclopharm said the capital raising would support rapid US commercialization following expected US Food and Drug Administration approval by July 2021.

Last week, Cyclopharm said the Society of Nuclear Medicine and Molecular Imaging had called on the US Food and Drug administration to expedite Technegas approval, after its phase III Technegas lung imaging trial closed early, with data from 200 patients meeting the primary efficacy endpoint (BD: Sep 15, 2020; Jan 17, 22, 2021).

On Monday, the company said the funds would be used to finance accelerated expansion into the US market, expand Technegas use beyond pulmonary embolism, ongoing research and development activities, product and systems enhancement, working capital and placement costs.

Cyclopharm managing-director James McBrayer said the capital raising “ensures that we are well positioned to rapidly commercialize in the US, following FDA approval”.

“Additionally, we will continue progressing our strategic initiatives including the expansion of the use of Technegas beyond the pulmonary embolism market and investing in ongoing research and development activities,” Mr McBrayer said.

Cyclopharm said it had “cornerstone” participation from Perennial Value Management, Investors Mutual and Regal Funds Management, along with support from existing large shareholders Karst Peak and Australian Ethical.

The company said record date for the share plan was January 22, the offer would open on February 1 and close on February 15, 2021.

Cyclopharm said it would pay a three percent management fee and two percent placement fee to Bell Potter Securities.

Cyclopharm was up 22 cents or 7.1 percent to \$3.32.

## GENETIC SIGNATURES

Genetic Signatures says it has Conformité Européenne in-vitro diagnostic (CE-IVD) registration for its Easyscreen STI genital pathogen detection kit.

Genetic Signatures said the Easyscreen sexually transmitted infection (STI) detection kit could simultaneously detect 10 of the most commonly encountered sexually transmitted infections.

Genetic Signatures chief executive officer Dr John Melki said the CE-IVD registration “was a significant achievement as we continue to execute on our global expansion strategy”.

“Sexually transmitted infections are a large and growing problem globally and we are pleased to be able to provide a high throughput and accurate diagnostic solution to improve patient outcomes,” Dr Melki said.

“Our company continues to work on new products and enhancing current product offerings even while we meet the substantial demand for our Easyscreen [Severe acute respiratory syndrome-cornavirus-2] Detection Kits,” Dr Melki said.

The company said that Australia Therapeutic Good Administration clearance for the Easyscreen STI detection kit was “anticipated soon”.

Genetic Signatures fell three cents or 1.5 percent to \$1.96.

## TELIX PHARMACEUTICALS

Telix says it has dosed the first US patients in its 250-patient, phase III Zircon trial of TLX250-CDx for imaging renal cancer.

Last year, Telix said the US Food and Drug Administration had approved the trial to assess the sensitivity and specificity of TLX250-CDx for the imaging of clear cell renal cell cancer using positron emission tomography (BD: Jan 23, 2020).

The company said the study had 12 clinical sites in the US and Canada and the first patients were being dosed at the University of California Los Angeles and the Seattle Cancer Care Alliance at the University of Washington, with 36 sites in Europe, Australian, North America and Turkey.

Telix fell six cents or 1.4 percent to \$4.30 with 882,130 shares traded.

## MACH7 TECHNOLOGIES

Mach7 says that Roseville, California-based Adventist Health System has expanded the contract for its picture archive communication system (PACS) and services.

Mach7 said the total contract value would be more than \$7.9 million, and included migration services and five years of support and maintenance, replacing the existing Adventist archive at 22 of its hospitals.

Mach7 was up eight cents or 5.5 percent to \$1.53 with 1.5 million shares traded.

## AROA BIOSURGERY

Aroa says its receipts from customers for the nine months to December 31, 2020 were \$NZ15,984,000 (\$A14,929,160).

Last year, Aroa said it listed on the ASX to commercialize of its sheep stomach-based soft tissue regeneration products and recorded revenue of \$NZ25.1 million for the 12 months to March 31, 2020 (BD: Jul 24, 2020).

The company said it had cash and cash equivalents of \$NZ36,815,000 at December 31, 2020 compared to \$NZ38,683,000 at September 30, 2020.

Aroa fell one cent or 0.96 percent to \$1.03 with 1.4 million shares traded.

### ELIXINOL GLOBAL

Elixinol says its receipts from customers for the year to December 31, 2020 fell 57.4 percent to \$14,095,000.

Elixinol said receipts for its marijuana food and drug products in the three months to December 31, 2020 were down 51.3 percent to \$3,265,000.

The company said sales came primarily from its hemp and cannabidiol (CBD)-based products, including its Good Mood 10mg CBD dietary supplement gummies.

Elixinol said it had cash and cash equivalents of \$27,743,000 at December 31, 2020 compared to \$20,373,000 at December 31, 2019.

Elixinol was unchanged at 19 cents with 4.3 million shares traded.

### ATOMO DIAGNOSTICS

Atomo says receipts from customers for the six months to December 31, 2020 were \$5,805,000 compared to \$2,654,000 for the year to June 30, 2020.

Last year, Atomo said it listed on the ASX to commercialize its HIV blood test and other rapid tests (BD: Apr 16, 2020).

Today, the company said receipts, mainly from sales of its Covid-19 rapid diagnostic test, for the three months to December 31, 2020 were down 8.8 percent to \$2,769,000 compared to the three months to September 30, 2020, with cash and equivalents of \$24,691,000 at December 31, 2020 compared to \$27,104,000 at June 30, 2020.

Atomo fell half a cent or 1.7 percent to 29.5 cents with 2.8 million shares traded.

### ANTERIS (FORMERLY ADMEDUS)

Anteris says its receipts from customers for the 12 months to December 31, 2020 fell 60.5 percent to \$7,278,000, compared to \$18,435,000 the previous year.

Anteris said customer receipts for the three months to December 31, 2020 were down 54.7 percent to \$1,312,000.

In 2019, BTC Health said it had completed its acquisition of the then Admedus hospital infusion business, a primary source of revenue for Admedus (BD: May 31, Aug 26, 2019).

Today, the company said receipts came primarily from payments for manufacturing Cardiocel and Vascucel patches for heart tissue repair under its agreement with the Burlington, Massachusetts-based Lemaitre Vascular Inc.

In 2019, the then Admedus said it had sold the distribution rights of Cardiocel and Vascucel to Lemaitre for up to \$36.2 million (BD: Oct 14, 15, 2019).

Anteris said it had cash and equivalents of \$4,353,000 at December 31, 2020 compared to \$8,968,000 at December 31, 2019.

Anteris fell 10 cents or 1.95 percent to \$5.02.

### USCOM

Uscom says its customer receipts for the six months to December 31, 2020 rose 146.25 percent to \$2,742,000, compared to the previous corresponding period.

Uscom said receipts from sales of its Uscom 1A ultra-sonic cardiac output monitor, Uscom BP+ blood pressure monitor, Spirosonic pulmonary function test and Ventitest ultrasonic ventilator calibration devices for the three months to December 31, 2020 were up 265.7 percent to \$1,413,000, and it had cash and equivalents of \$2,278,000 at December 31, 2020 compared to \$1,483,006 at December 31, 2019.

Uscom was unchanged at 16 cents.

### MEDLAB CLINICAL

Medlab says receipts from customers for the six months to December 31, 2020 was down 36.5 percent to \$2,568,000, compared to the previous corresponding period.

Medlab said receipts from customers for its food additives and marijuana products fell 23.5 percent to \$1,255,000 in the three months to December 31, 2020.

The company said it had cash and equivalents of \$6,877,000 at December 31, 2020.

Medlab fell 1.5 cents or 4.4 percent to 32.5 cents.

### IQ3 CORP

IQ3 says its receipts from customers for the six months to December 31, 2020 were down 42.5 to \$2,505,000, compared to \$4,359,000 at December 31, 2019.

IQ3 said receipts from sales of its corporate advisory services to companies in the life sciences industry for the three months to December 31, 2020 fell 57.4 percent to \$1,082,000.

The company said it had cash and cash equivalents of \$652,000 at December 31, 2020 compared to \$453,000 at December 31, 2019.

IQ3 was untraded at 30 cents.

### CELLMID

Cellmid says receipts from customers for the six months to December 31, 2020 fell 27.0 percent to \$3,484,000, compared to the previous corresponding period.

Cellmid said that for the three months to December 31, 2020, receipts from customers for its hair growth products, were down 35.6 percent to \$1,397,000.

Separately, the company said the Hong Kong-based Ourui Health Management had ordered its first 66,000 bottles of Jo-Ju shampoo to be delivered in bulk "as no import permit has been received for the fully finished shampoo yet" and would be packaged at Ourui's cost.

Cellmid said that it had received an order for 18,672 bottles of fully finished Jo-Ju lotions had been received with an import permit.

The company said the combined orders were valued at \$530,000.

In December 2020, the company said its Advangen subsidiaries have appointed Ourui Health Management to distribute its Ju-Ju and Lexilis anti-aging hair and skincare products in China (BD: Dec 14, 2020).

Cellmid fell half a cent or 4.35 percent to 11 cents.

### PHARMAUST

Pharmaust says receipts from customers for the six months to December 31, 2020 fell 26.8 percent to \$1,321,000, compared to the previous corresponding period.

Pharmaust said that receipts, primarily from its Epichem medicinal chemistry division, for the three months to December 31 were down 22.7 percent to \$549,000.

The company said it had cash and cash equivalents of \$3,610,000 at December 31, 2020 compared to \$2,922,000 at December 31, 2019.

Pharmaust was unchanged at 10.5 cents with 2.3 million shares traded.

## 4D MEDICAL

4D says it has started a US pilot program of its x-ray velocimetry lung ventilation analysis software (XV LVAS) diagnostic at California's St Joseph Hospital.

Last year, 4D said the XV LVAS had been approved by the US Food and Drug Administration and the Therapeutic Goods Administration (BD: May 21; Sep 30, 2020).

Today, the company said the program at the Orange County-based St Joseph Hospital would assess how the XV technology could help hospital physicians screen for a variety of lung conditions, including asthma, emphysema, pulmonary fibrosis, lung cancer and Covid-19.

4D said the program was the beginning of its commercialization phase in the US and it would allow hospitals and medical institutions to implement and trial its technology ahead of potential commercial integration.

4D chief executive officer Dr Andreas Fouras said the company believed the XV LVAS could "assist physicians in diagnosing and managing patients with various lung diseases, including Covid-19, as it provides physicians with a unique picture of how air moves in the lungs".

4D fell one cent or 0.4 percent to \$2.25 with 909,024 shares traded.

## HERAMED

Heramed says the Fortazela, Brazil-based Hapvida will pay \$US45,000 (\$A58,110) for a two-year extension to its Heracare pregnancy monitoring software subscription.

In 2019, Heramed said it had installed its Herabeat foetal heart rate monitors and Heracare software at multiple Hapvida hospitals in Brazil (BD: Jul 1, Aug 28, 2019).

Today, the company said the software agreement had been updated to include "a per user per month" subscription model but did not disclose the monthly user cost.

Heramed said negotiations with Hapvida were on going in relation to the purchase of additional Herabeat devices.

Heramed fell half a cent or 4.35 percent to 11 cents.

## IMMUTEP

Immutep says it will begin enrolment for the randomized portion of its up-to 110 patient phase II trial of IMP321 for Covid-19 following a positive trial safety review.

Last year, Immutep said it had an agreement with the Czech Republic's University Hospital Pilsen for a placebo-controlled, randomized, double-blinded phase II trial of IMP321, or efitlagimod alpha, to investigate whether early administration of IMP321 could prevent disease progression in hospitalized adult Covid-19 patients, by boosting the patient's immune response (BD: Oct 23, 2020).

Today, the company said an independent data and safety monitoring board reviewed data from the first six patients in the trial and recommended that the study advance with enrolment for the randomized portion of the study.

Immutep chief scientific officer Dr Frédéric Triebel said there was "a significant need to develop therapeutics like efitlagimod alpha to treat Covid-19 inpatients with an insufficient immune response to overcome the viral spread".

Immutep said the primary endpoint of the trial was the patient's clinical status at day-15 as per the World Health Organisation recommended evaluation scale.

Immutep was up three cents or 7.2 percent to 44.5 cents with 4.1 million shares traded.

### UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed the Windsor, California-based Enartis Inc to distribute its Sentia wine sulphur dioxide analyzer in the US.

Universal Biosensors chief executive officer John Sharman said the company's "first order of 1,000 Sentia devices arrived in our Rowville warehouse last week and we are preparing to ship Sentia product to the US and to our Australian partners during January".

Universal Biosensors was up two cents or 4.35 percent to 48 cents.

### EMVISION MEDICAL DEVICES

Emvision says the US Food and Drug Administration has recommended using the "de-novo" regulatory pathway for its portable brain scanner

Emvision said the de-novo pathway was "designed for low to moderate-risk, first-of-a-kind products and [employed] a risk-based strategy for evaluating applications".

The company said it would engage with the FDA to confirm the required evidence including the clinical data necessary to support the submission as well as an application for the FDA breakthrough device program.

Emvision fell eight cents or 2.7 percent to \$2.84.

### SUDA PHARMACEUTICALS

Suda says Mitsubishi Tanabe Pharma Singapore intends "not to proceed" with the licence and supply agreement for its Zolpimist oral spray for insomnia.

Suda said that the Singapore-based Mitsubishi Tanabe Pharma had changed its business strategy for the Association of South East Asian Nations (ASEAN) region.

In 2018, the company said it would licence Zolpimist to Mitsubishi Singapore for up to \$US980,000 for Singapore, Malaysia and the Philippines, with a 12-month option on Thailand, Indonesia, Vietnam, Myanmar, Cambodia, Laos and Brunei (BD: Dec 19, 2018).

Last year, Suda said South Korea's Mitsubishi Tanabe Pharma Korea would pay up-to \$US500,000 (\$A869,600) plus royalties for a 10-year licence to its Zolpimist, including an upfront fee of \$US100,000, as well as a \$US100,000 milestone payment based on Mitsubishi Korea obtaining regulatory approval and sales target-based milestone payments of up to \$US300,000

Today, Suda chief executive officer Dr Michael Baker told Biotech Daily that the South Korea licence continued unaffected by the Singapore decision.

Suda said there would be no immediate impact on revenue streams, and it would "look to secure additional partners for the ASEAN region and other territories".

Suda was up 0.2 cents or five percent to 4.2 cents with 2.4 million shares traded.

### LITTLE GREEN PHARMA

Little Green says it has been appointed as a supplier for a two-year French national trial of medical marijuana for conditions resistant to conventional treatments.

Little Green said the trial was run in partnership with the Saint Cloud, Ile de France-based pharmaceutical distributor, Intsel Chimos.

The company said the trial would be the only pathway for the supply of medical marijuana into France for next two years, and it expected to have an advantage in the future market.

Little Green said it was the trial's primary supplier for two cannabidiol (CBD)-dominant oil medicines and the back-up supplier for a tetrahydrocannabinol and CBD oil medicine.

Little Green was up seven cents or 12.1 percent to 65 cents with 1.6 million shares traded.

### [BTC HEALTH](#)

Sydney's Naos Substantial Holders says it has increased its substantial shareholding in BTC from 64,478,325 shares (26.20%) to 67,507,793 shares (27.43%).

Naos said it acquired 3,029,468 shares for \$276,571 or 9.13 cents a share.

BTC was unchanged at 8.9 cents.

### [ANTERIS TECHNOLOGIES \(FORMERLY ADMEDUS\)](#)

New York's Mercer Street Global Opportunity Fund says it has become a substantial shareholder in Anteris with 341,545 shares or 5.20 percent of the company.

Mercer Street said it bought 291,545 shares on January 20, 2020 for \$1,000,000 and received 50,000 "commencement" shares relating to its finance facility (BD: Jan 18, 2021).

### [LIVING CELL TECHNOLOGIES](#)

Living Cell says Dr Ken Taylor intends to resign as the chief executive officer effective from July 2021.

Living Cell said Dr Taylor was appointed as chief executive officer in February 2014 and as a director in August 2014 (BD: Apr 1, Jul 8, 2014).

Living Cell chair Prof Bernie Tuch said the company had "benefited greatly from Dr Taylor's connections and reputation in the global pharmaceutical industry".

Prof Tuch said that in Dr Taylor's seven years, the company completed two clinical studies of NTCell for Parkinson's disease, initiated projects for migraine and obesity and Dr Taylor connected Living Cell with relevant experts and brought in new investors.

Living Cell fell 0.1 cents or 5.9 percent to 1.6 cents.

### [CSL](#)

CSL says director Dr Pascal Soriot has resigned to avoid any potential "conflict of strategic interest between CSL and Astrazeneca" effective from February 1, 2021.

In July 2020, CSL said it appointed Astrazeneca chief executive officer Dr Soriot as a director, and in September said it had an agreement to manufacture 30 million doses of the Oxford University Astrazeneca Sars-Cov-2 vaccine (BD: Jul 16; Sep 7, 2020).

Today, the company said Dr Soriot's resignation related to the acquisition of the Boston Massachusetts-based Alexion by Astrazeneca.

CSL fell 34 cents or 0.1 percent to \$275.20 with 1.05 million shares traded.

### [FACTOR THERAPEUTICS](#)

Factor says Taylor Collison has been appointed to assist broaden its commercial opportunities, particularly in areas beyond the board's expertise in biotechnology.

Last week, Factor said it had ceased negotiations with Longmile Veterinary (positron emission tomography) PET Imaging, citing delays in ASX advice (BD: Jan 18, 2021).

This week, the company said the Sydney-based Taylor Collison had expertise in biotechnology, resources, technology and industrial businesses.

Factor was in a suspension at half a cent.