



# Biotech Daily

Monday January 31, 2022

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: NEXT SCIENCE UP 15%; RESONANCE DOWN 6%**
- \* **CLINUVEL H1 RECEIPTS UP 79% TO \$31m**
- \* **LUMOS H1 RECEIPTS \$8.2m**
- \* **MESOBLAST H1 RECEIPTS UP 181% TO \$7.9m**
- \* **PHARMAXIS H1 RECEIPTS UP 101% TO \$7.2m**
- \* **NEXT SCIENCE RECEIPTS UP 223% to \$13.6m**
- \* **IMEX RECEIPTS UP 25% TO \$11m**
- \* **IMPEDIMED H1 RECEIPTS UP 53% TO \$5.1m**
- \* **CRESO RECEIPTS UP 71% TO \$6.4m**
- \* **NUHEARA H1 RECEIPTS DOWN 48% TO \$2.8m**
- \* **PHARMAUST (EPICHEM) H1 RECEIPTS UP 31% TO \$1.7m**
- \* **RESONANCE H1 RECEIPTS DOWN 12.3% TO \$1.7m**
- \* **CARDIEX H1 RECEIPTS DOWN 26% TO \$1.7m**
- \* **BIOXYNE H1 RECEIPTS UP 30% TO \$1.7m**
- \* **DORSAVI H1 RECEIPTS UP 112% TO \$1.6m**
- \* **OSPREY RECEIPTS UP 7% TO \$2.8m**
- \* **IDT FEDERAL SUPPLY DEAL ENDS, 'mRNA DISCUSSION ONGOING'**
- \* **PHARMAXIS DOSES 1st PATIENTS IN PXS-6302 SCAR REDUCTION TRIAL**
- \* **ALLEGRA CLAIMS SR-HT-GAHNITE SPINAL CAGE SHEEP TRIAL SUCCESS**
- \* **NEXT SCIENCE APPOINTS ZIMMER US XPERIENCE DISTRIBUTOR**
- \* **EXOPHARM, ASTELLAS \$686k EXOSOME COLLABORATION**
- \* **IMUGENE: CF33, VAXINIA, CHECKVACC JAPAN PATENT**
- \* **TELEX DR BEHRENBRUCH, ELK RIVER; GNOSIS, DR KLUGE REDUCE TO 7.4%**
- \* **MERCHANT FUNDS TAKES 8% OF AROVELLA**
- \* **MTP CONNECT LOSES M-D DR DAN GRANT; COO STUART DIGNAM INTERIM**
- \* **OVENTUS JOHN COX CEO ON \$534k; DR CHRIS HART DIRECTOR, ADVISER**
- \* **INVEX: CHAIR DR LOVERIDGE \$276k; CSO PROF ALEX SINCLAIR \$281k**
- \* **RACE APPOINTS CHRISTINA MANFRE CFO**

## MARKET REPORT

The Australian stock market fell 0.24 percent on Monday January 31, 2022, with the ASX200 down 16.5 points to 6,971.6 points.

Twenty-five of the Biotech Daily Top 40 companies were up, 10 fell and five traded unchanged.

Next Science was the best, up 16 cents or 15.2 percent to \$1.21, with 271,735 shares traded.

Genetic Signatures and Impedimed improved more than nine percent; Telix and Volpara climbed more than eight percent; Medical Developments and Neuren were up more than five percent; Immutep, Kazia and Patrys were up more than four percent; Cochlear, Mesoblast and Starpharma improved more than three percent; Compumedics, Micro-X, Proteomics, Resmed and Uscom rose more than two percent; Avita, CSL, Cyclopharm, Nova Eye, Opthea, Paradigm and Pharmaxis were up more than one percent; with Clinuvel, Nanosonics and Pro Medicus up by less than one percent.

Resonance led the falls, down one cent or 6.25 percent to 15 cents, with 132,571 shares traded.

Actinogen fell four percent; Cynata lost 3.1 percent; Antisense, Atomo, Dimerix and Oncosil shed more than two percent; with Emvision, Imugene and Universal Biosensors down by less than one percent.

## CLINUVEL PHARMACEUTICALS

Clinuvel says receipts from customers for the six months to December 31, 2021 was up 78.8 percent to \$30,905,000 compared to the prior corresponding period.

Clinuvel said its receipts from customers for its Scenesse photosensitivity treatment for erythropoietic protoporphyria for the three months to December 31, 2021 was up 149.1 percent to \$13,120,000 compared to the prior corresponding period.

The company said that it was \$5,746,000 cashflow positive for the three months to December 31, 2021, with cash and equivalents of \$98,993,000 compared to \$72,918,000 at December 31, 2020.

Clinuvel was up 21 cents or 0.9 percent to \$23.02 with 148,100 shares traded.

## MESOBLAST

Mesoblast says customer receipts for the six months to December 31, 2021 rose 180.5 percent to \$US5,531,000 (\$A7,914,000) compared to the prior corresponding period.

Mesoblast said that receipts, primarily from Temcell royalties for graft-versus-host-disease in Japan, for the three months to December 31, 2021 were up 174.1 percent to \$US3,536,000.

The company said it had a cash burn for the three months to December 31, 2021 of \$US19,763,000, with cash and cash equivalents of \$US94,894,000 at December 31, 2021 compared to \$US77,528,000 at December 31, 2020.

Mesoblast was up 3.5 cents or 3.2 percent to \$1.125 with 2.1 million shares traded.

## PHARMAXIS

Pharmaxis says receipts from customers for the six months to December 31, 2021 were up 101.4 percent to \$7,255,000 compared to the prior corresponding period.

Pharmaxis said its receipts from customers for its Aridol bronchial challenge test and Bronchitol cystic fibrosis treatment for the three months to December 31, 2021 were up 125.2 percent to \$3,757,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$3,737,000 for the three months to December 31, 2021, with cash and equivalents of \$20,866,000 compared to \$18,249,000 at December 31, 2020.

Pharmaxis was up 0.1 cents or one percent to 10 cents with 1.045 million shares traded.

## LUMOS DIAGNOSTICS

Lumos says that receipts from customers for the six months to December 31, 2021 were \$US5,735,000 (\$A8,181,000).

Lumos listed on the ASX last year in July to commercialize its Febridx point-of-care test to differentiate viral from bacterial infections and develop Covidx its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen test (BD: Jul 9 2021).

Lumos said that receipts from customers for the three months to December 31, 2021 were \$US1,626,000.

The company said it had a cash burn for the three months to December 31, 2021 was \$US5,872,000, with cash and cash equivalents of \$US10,465,000 at December 31, 2021.

Lumos fell six cents or 6.3 percent to 89 cents.

## NEXT SCIENCE

Next Science says customer receipts for the year to December 31, 2021 was up 222.5 percent to \$US9,513,000 (\$A13,596,000) compared to the prior corresponding period.

Next Science said that receipts, primarily from its Xperience surgical wash, for the three months to December 31, 2021 rose 956.3 percent to \$US2,947,000.

The company said it had a cash burn for the three months to December 31, 2021 of \$US2,081,000, with cash and equivalents of \$US7,368,000 at December 31, 2021 compared to \$US15,339,000 at December 31, 2020.

Next Science was up 16 cents or 15.2 percent to \$1.21.

## IMEX HEALTH SERVICES

Imex says receipts from customers for the 12 months to December 31, 2021 was up 24.5 percent to \$10,855,000 compared to the prior corresponding period.

Imex said its receipts from customers for its Aquila internet-based radiology and imaging software for the three months to December 31, 2021, was up 74.5 percent to \$4,128,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$447,000 for the three months to December 31, 2021, with cash and equivalents of \$4,186,000 compared to \$10,845,000 at December 31, 2020.

Imex was up 6.5 cents or 6.8 percent to \$1.015.

### IMPEDIMED MEDICAL

Impedimed says receipts from customers for the six months to December 31, 2021 was up 52.7 percent to \$5,096,000 compared to the previous corresponding period.

Impedimed said that receipts from sales of its Sozo bioimpedance spectroscopy devices, as well as service as a software revenue for the three months to December 31, 2021 rose 27.8 percent to \$2,605,000.

The company said it had a cash burn for the three months of \$2,946,000, with cash and cash equivalents of \$50,807,000 at December 31, 2021 compared to \$19,021,000 at December 31, 2020.

Impedimed was up 1.5 cents or 9.4 percent to 17.5 cents with 3.5 million shares traded.

### CRESO PHARMA

Creso says receipts from customers for the 12 months to December 31, 2021 was up 70.8 percent to \$6,409,000 compared to the prior corresponding period.

Creso said its receipts from customers for its recreational and medical marijuana products for the three months to December 31, 2021, was up 221.7 percent to \$2,281,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$4,424,000 for the three months to December 31, 2021, with cash and equivalents of \$7,062,000 compared to \$6,004,000 at December 31, 2020.

Creso was up 0.2 cents or 2.5 percent to 8.2 cents with 2.3 million shares traded.

### NUHEARA

Nuheara says receipts from customers for the six months to December 31, 2021 were down 47.6 percent to \$2,798,000 compared to the prior corresponding period.

Nuheara said its receipts from customers for its sound filtering and hearing ear-buds for the three months to December 31, 2021, were down 65.3 percent to \$1,672,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$763,000 for the three months to December 31, 2021, with cash and equivalents of \$6,523,000 compared to \$2,396,000 at December 31, 2020.

Nuheara was unchanged at 1.6 cents with 5.7 million shares traded.

### PHARMAUST

Pharmaust says receipts from customers for the six months to December 31, 2021 was up 30.5 percent to \$1,724,000 compared to the prior corresponding period.

Pharmaust said its receipts from customers, primarily from its wholly-owned Epichem subsidiary's medicinal chemistry contracts, for the three months to December 31, 2021 were up 67.9 percent to \$922,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$656,000 for the three months to December 31, 2021, with cash and equivalents of \$2,644,000 compared to \$3,610,000 at December 31, 2020.

Pharmaust fell 0.1 cents or one percent to 9.8 cents.

## RESONANCE HEALTH

Resonance says receipts from customers for the six months to December 31, 2021 was down 12.3 percent to \$1,705,000 compared to previous corresponding period.

Resonance said that receipts from its Ferriscan liver imaging products and related software for the three months to December 31, 2021 fell 0.6 percent to \$997,000.

The company said it had a cash burn for the three months to December 31, 2021 of \$283,000, cash and cash equivalents of \$7,835,000 at December 31, 2021, compared to \$8,108,000 at December 31, 2020.

Resonance fell one cent or 6.25 percent to 15 cents.

## CARDIEX

Cardiex says receipts from customers for the six months to December 31, 2021 were down 25.8 percent to \$1,704,000 compared to the prior corresponding period.

Cardiex said receipts from customers for its vital signs wearable sensors for the three months to December 31, 2021, were down 1.2 percent to \$1,019,000 compared to the prior corresponding period.

The company said that it had a cash burn of \$2,708,000 for the three months to December 31, 2021, with cash and equivalents of \$5,465,000 compared to \$3,322,000 at December 31, 2020.

Cardiex was unchanged at five cents with 3.8 million shares traded.

## BIOXYNE

Bioxyne says receipts from customers for the six months to December 31, 2021 were up 30.25 percent to \$1,666,000 compared to the prior corresponding period.

Bioxyne said its receipts from customers for its Lactobacillus fermentum PCC probiotics for the three months to December 31, 2021 was up 53.6 percent to \$1,058,000 compared to the prior corresponding period.

The company said that it was \$317,000 cashflow positive for the three months to December 31, 2021, with cash and equivalents of \$2,074,000 compared to \$1,769,000 at December 31, 2020.

Bioxyne fell 0.1 cents or 4.2 percent to 2.3 cents.

## DORSAVI

Dorsavi says receipts from customers for the six months to December 31, 2021 was up 112.0 percent to \$1,560,000 compared to the prior corresponding period.

Dorsavi said its receipts from customers for its wearable movement sensors and consulting services for the three months to December 31, 2021 was up 65.2 percent to \$532,000 compared to the prior corresponding period.

The company said it had a cash burn of \$415,000 for the three months to December 31, 2021, with cash and equivalents of \$2,144,000 compared to \$2,946,000 at December 31, 2020.

Dorsavi fell 0.1 cents or five percent to 1.9 cents.

## OSPREY MEDICAL

Osprey says receipts from customers for the year to December 31, 2021 were up 6.9 percent to \$US1,966,000 (\$A2,805,000) compared to the prior corresponding period. Osprey said that receipts revenue from its Dyevert cardiac dye reduction system for the three months to December 31, 2021 fell by 7.3 percent to \$US446,000.

Osprey chief executive officer Mike McCormick said the fall was due to “most of our key target markets experienced an alarming resurgence of Covid cases”.

“Osprey’s sales figures have remained resilient and were bolstered by consistent [outside US] sales,” Mr McCormick said.

The company said it had a cash burn for the three months to December 31, 2021 of \$US2,675,000, with cash and cash equivalents of \$US5,386,000 at December 31, 2021 compared to \$US5,787,000 at December 31, 2020, but provided no further details.

Osprey was up 4.5 cents or 10.3 percent to 48 cents.

## IDT AUSTRALIA

IDT says its Sterile Readiness Agreement with the Federal Government has ended but discussions are continuing regarding mRNA product translation and manufacturing.

Last year, IDT said it had an agreement with the Federal Government “to ensure the production capacity of its sterile facility would be retained exclusively for Health ...until the earlier of executing a supply agreement to deliver a Covid-19 vaccine, or four months from completion of [its] sterile readiness works” (BD: Jun 22, Aug 20, 2021).

The company said that the exclusivity period had “come to an end”.

In December, IDT said that its submission to the Federal Government to establish an onshore mRNA manufacturing capability “has not been selected to progress to the next stage” (BD: Dec 16, 2021).

In November, IDT said that with Monash University’s Institute of Pharmaceutical Sciences it had manufactured severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) mRNA vaccine, the drug product “met all specifications” and was progressing through the release process to be supplied to MIPS for their clinical trial (BD: Nov 30, 2021).

On December 14, the Federal Government announced with the Victoria Government that a new factory would be built in Victoria with Moderna to produce respiratory mRNA vaccines in the onshore mRNA approach to market (ATM) process (BD: Dec 14, 2021).

Today, IDT said that it was “in active discussions” with the Federal Government on several fronts regarding mRNA product translation and manufacturing, including applications to both the Collaboration Stream and the Translation Stream of the Government’s Modern Manufacturing Initiative fund.

The company said that both of its applications remained live.

IDT was up 1.5 cents or 6.8 percent to 23.5 cents.

## PHARMAXIS

Pharmaxis says it has dosed its first of 50 patients in a 12-week, placebo-controlled, phase Ic, safety and tolerability trial of PXS-6302 for scar reduction.

Last year, Pharmaxis said PXS-6302 was safe and well tolerated, with full inhibition of lysyl oxidase enzymes in skin with minimal systemic exposure (BD: Aug 31, 2021).

Today, the company said it would dose eight adult patients who had scars between one and five years duration, with the second cohort of 42 patients being split equally between active treatment and placebo.

Pharmaxis said the trial at Perth’s Fiona Stanley Hospital was led by Prof Fiona Wood.

## ALLEGRA ORTHOPAEDICS

Allegra says that all animals in its sheep study have had its Sr-HT-Gahnite Spinal Cage Device “implanted successfully”.

Allegra previously said that Sr-HT-gahnite was composed of strontium, hardystonite (a calcium-zincsilicate) and gahnite, a zinc-aluminium-oxide (BD: Jun 8, Sep 20, 2016).

Allegra said that the study, at the South Australian Health and Medical Research Institute’s Preclinical, Imaging and Research Laboratories had “entered into its final stages with all animals implanted successfully”.

The company said that the Institute reported that “the animals have coped well with the surgery ... with no in-life complications associated with the procedures to date”.

Allegra said that at 18 weeks post-surgery the sheep had been regularly scanned by computed tomography (CT) to monitor the progression of the fusion site and “all surgical sites are progressing well”.

The company said that a 13-week cohort reached completion with “no gross adverse biocompatibility issues ... observed”.

Allegra said that there was “good evidence of fusion at the operated level”.

The company said that histological analyses would be performed following the completion of the in-life phase to provide further evidence of successful spinal fusion.

Allegra said that positive results from the study would “confirm a viable pathway” to obtaining a 90-day US Food and Drug Administration 510(k) clearance in the near future.

The company said the Sr-HT-Gahnite material would be used for a broad range of applications including spine, hip, knee and extremities.

Allegra was untraded at 12.5 cents.

## NEXT SCIENCE

Next Science says it has a five-year agreement for the Warsaw, Indiana-based Zimmer Biomet to distribute its Xperience leave-in surgical wash in the US.

Next Science said that as part of the agreement, Zimmer would drop the commercial exclusivity complaint it had brought against Next Science in the US District Court at the Northern District of Indiana (BD: Jun 24, 2021).

Next Science managing-director Judith Mitchell said the new arrangements “provide a paradigm shift in the representation of Xperience to the US orthopaedic market”.

“The Zimmer joint-replacement sales team is a well-credentialed, market-leading commercial force in the orthopaedic market and we look forward to the positive impact it can have ... for the white-labelled version of our Xperience product,” Ms Mitchell said.

## EXOPHARM

Exopharm says the Astellas Institute for Regenerative Medicine will pay it \$US481,000 (\$A686,000) for collaboration on exosomes.

Exopharm said that under the agreement, the Westborough, Massachusetts-based Astellas Institute, a subsidiary of the Tokyo-based Astellas Pharma Inc, would validate the platforms Exopharm used to manufacture its exosomes, after which Exopharm would provide Astellas with exosomes, the first from its Melbourne factory, and then at Astellas facilities in the US.

Exopharm chief commercial officer Dr Chris Baldwin said the contract was “a major milestone for us in its own right, but it is also the crucial first step for any drug development partnership in the future”.

Exopharm was up five cents or 11.6 percent to 48 cents.

## IMUGENE

Imugene says the Japan Patent Office has granted a patent for CF33, the oncolytic virotherapy underpinning its Vaxinia and Checkvacc drug candidates.

Imugene said that the patent, titled 'Chimeric Poxvirus Composition And Uses Thereof' would protect its intellectual property until 2037.

Imugene fell half a cent or 1.6 percent to 31 cents with 44.9 million shares traded.

## TELIX PHARMACEUTICALS

Elk River Holdings as trustee for the Behrenbruch family says it has reduced its Telix holding from 24,675,000 shares (8.66%) to 22,675,000 shares (7.38%).

Gnosis Verwaltungsgesellschaft and Telix co-founder Dr Andreas Kluge say they reduced their Telix holding from 24,675,000 shares (8.66%) to 22,675,000 shares (7.38%).

Last week, Telix said that chief executive officer Dr Chris Behrenbruch and Dr Kluge sold 2,000,000 shares each as part of the recent capital raising (BD: Jan 24, 2021).

Telix was up 55 cents or 8.8 percent to \$6.79 with 1.1 million shares traded.

## AROVELLA THERAPEUTICS (SUDA PHARMACEUTICALS)

The Perth-based Merchant Funds Management says it has become a substantial shareholder in Arovella with 47,416,660 shares or 7.89 percent.

Merchant said it bought the shares on January 27 and 28, 2022 for 3.8 cents a share.

Last week, Arovella said that it raised \$4.57 million in a placement at 3.9 cents a share and expected to raise a further \$1.5 million in a share plan (BD: Jan 24, 2022).

Arovella was up 0.1 cents or 2.6 percent to four cents with 1.6 million shares traded.

## MTP CONNECT

MTP Connect says that managing director Dr Dan Grant has resigned, with chief operating officer Stuart Dignam appointed as interim chief executive officer.

MTP Connect said that Dr Grant was appointed chief executive officer in July 2018 when the organization was responsible for the \$15.6 million Growth Centre Project Fund and a \$10 million program from the Medical Research Future Fund (MRFF) with a team of six.

The Federally-funded industry organization said it currently had more than \$180 million in project funds under management and 24 staff members.

"I am so proud of our team at MTP Connect," Dr Grant said. "We've built the organization to be a significant player in Australia's medical products landscape."

"When you look at the funding allocated through our granting programs, the additional contributions provided by industry, the flow-on external investments and the money secured through grant reviews, MTP Connect has contributed to \$968 million flowing into Australia's medical products sector," Dr Grant said.

MTP Connect chair Sue MacLeman thanked Dr Grant for "his outstanding contribution to MTP Connect and the growth of the ... sector".

The organization said it would undertake a search for a new chief executive officer.

MTP Connect said that chief operating officer Stuart Dignam had been appointed interim chief executive officer.

The organization said that Mr Dignam was appointed to the company in August 2018 and previously worked for CPA Australia, was the Queensland Government's deputy trade and investment commissioner for the Americas, had worked as a broadcaster for ABC Radio and as a government media and policy advisor.



## OVENTUS MEDICAL

Oventus says that executive director Dr Chris Hart will be replaced as chief executive officer by John Cox, starting on \$US375,000 (\$A534,257) on February 1, 2022.

Oventus said that Dr Hart would be paid \$US340,000 (\$A484,357) as chief scientific officer and executive director until May 31, 2022, to aid Mr Cox's introduction to the role.

The company said that from June 1, 2022, Dr Hart would be a non-executive director and lead its scientific advisory board.

Oventus chair Sue MacLeman thanked Dr Hart "for his leadership and the many significant contributions".

"He invented the technology, founded the company, and has led Oventus through its early stages with conviction and passion," Ms MacLeman said.

Oventus said that Mr Cox had more than 30 years' experience in medical technologies, including in sleep apnoea and therapeutic technology marketing and operations.

The company said that previously Mr Cox was Somnera Inc's chief executive officer and prior to that worked for USGI Medical, B Braun Aesculap, Applied Medical and Covidien.

Oventus said that Mr Cox was the named inventor or co-inventor for more than 30 US patents.

The company said that Mr Cox held a Bachelor of Arts and a Master of Business Administration from the University of Virginia.

Oventus fell 0.2 cents or three percent to 6.5 cents.

## INVEX THERAPEUTICS

Invex says that it has signed contracts with chair Dr Jason Loveridge and chief scientific officer and executive director Prof Alexandra Sinclair.

Invex said that Dr Loveridge would receive a \$60,000 non-executive chairman fee, as well as a GBP110,000 (\$A211,000) consultancy fee, and would be eligible to participate in Invex's employee securities incentive plan.

The company said that Prof Sinclair would work three days a week in return for GBP145,000 (\$A278,000) as well as a GBP1,320 (\$A2,526) pension contribution, and would be eligible for the incentive plan.

Invex was unchanged at 61 cents.

## RACE ONCOLOGY

Race says it has appointed Christina Manfre as its chief financial officer.

Race said Ms Manfre was a partner at PKF Sydney.

The company told Biotech Daily that Ms Manfre held a Bachelor of Applied Finance and a Bachelor of Commerce from Sydney's Macquarie University.

Race was up 13 cents or 4.4 percent to \$3.06.