



# Biotech Daily

Tuesday January 31, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX FLAT, BIOTECH DOWN: CYNATA UP 10%; USCOM DOWN 12%**
- \* **SWINBURNE: WOKE TO PAY \$5m FOR PSILOCYBIN DEPRESSION TRIAL**
- \* **CLINUVEL H1 RECEIPTS UP 17% TO \$36m**
- \* **NOVA EYE H1 SALES UP 28% TO \$8m**
- \* **IMEX RECEIPTS UP 50% TO \$16m**
- \* **ACADIA MILESTONE TAKES NEUREN RECEIPTS TO \$16m**
- \* **VISIONEERING RECEIPTS UP 2.1% TO \$11.3m**
- \* **CRESO RECEIPTS UP 29% TO \$8m; 2.01 QUARTERS CASH**
- \* **OVENTUS IP SOLD FOR \$500k TO OPEN AIRWAY DENTAL**
- \* **ONCOSIL: ISRAEL, SPAIN USE PANCREATIC CANCER DEVICE**
- \* **PROTEOMICS FURTHER EXTENDS SONIC PROMARKED INTENT**
- \* **MERCHANT LOSES ALL HEXIMA SPILL EGM RESOLUTIONS**
- \* **REGENEUS, KYOCERA PROGENZA DEAL TERMINATION**
- \* **CENTENARY APPOINTS PROF MARC PELLEGRINI EXECUTIVE DIRECTOR**
- \* **STARPHARMA APPOINTS DR RUSSELL BASSER DIRECTOR**
- \* **RHYTHM APPOINTS SUE MACLEMAN DIRECTOR**

## MARKET REPORT

The Australian stock market slipped 0.07 percent on Tuesday January 31, 2023, with the ASX200 down 5.0 points to 7,476.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell, four traded unchanged and one was untraded. All three Big Caps rose.

Cynata was the best, up three cents or 9.7 percent to 34 cents, with 55,000 shares traded. Resonance rose 9.4 percent; Patrys climbed 6.9 percent; Amplia improved 4.7 percent; Impedimed, Kazia and Micro-X were up more than three percent; Oncosil and Resmed rose more than two percent; Cochlear, CSL, Pharmaxis and Pro Medicus were up more than one percent; with Avita, Nanosonics and Polynovo up by less than one percent.

Uscom led the falls, down 0.6 cents or 11.8 percent to 4.5 cents, with 15,600 shares traded. Clinuvel lost 11.0 percent; Starpharma fell 8.1 percent; Next Science shed 6.8 percent; Compumedics was down 5.3 percent; Genetic Signatures and Volpara fell more than four percent; Alcidion and Imugene were down more than three percent; Antisense, Nova Eye, Orthocell, Paradigm and Proteomics shed more than two percent; Actinogen, Atomo, Medical Developments and Universal Biosensors were down one percent or more; with Emvision, Mesoblast, Neuren and Telix down by less than one percent.

### [SWINBURNE UNIVERSITY, WOKE PHARMACEUTICALS](#)

Swinburne University says Woke will pay \$5 million for a 160-patient, randomized, controlled trial of psilocybin-assisted psychotherapy for depression.

Swinburne said that the trial would use mushroom-derived psilocybin with psychotherapy compared to a placebo with psychotherapy with enrolment to begin in mid-2023.

Last year, Woke said it would conduct a phase IIb trial of 25mg WP002 with psychotherapy for treatment-resistant depression, with enrolment expected to begin in early 2023, and led by Swinburne's Prof Susan Rossell (BD: Aug 16, 2022).

The company said at that time the primary outcome was a measure of depression after 12 weeks using the Montgomery-Asberg depression rating scale, with secondary measures including psychological measures for behaviour, "wellness" and quality of life.

Woke chief executive officer Nick Woolf said the trial would "inform the further development and potential registration of WP002 psilocybin-assisted psychotherapy as an effective treatment approach for patients living with this debilitating condition".

"In addition, the trial will investigate the potential economic benefits to the healthcare system and society from durable remission of depression," Mr Woolf said.

Mr Woolf told Biotech Daily that the \$5 million payment would be spread over the life of the trial, expected to take about two years.

Woke is a private company.

### [CLINUVEL PHARMACEUTICALS](#)

Clinuvel says receipts from customers for the six months to December 31, 2022 was up 16.9 percent to \$36,134,000 compared to the prior corresponding period.

Clinuvel said receipts for its Scenesse photosensitivity treatment for erythropoietic protoporphyria for the three months to December 31, 2022 were down 19.0 percent to \$10,623,000 compared to the previous corresponding period.

The company said it was \$3,726,000 cash flow positive with cash and equivalents of \$140,703,000 at December 31, 2022, compared to \$98,993,000 at December 31, 2021. Clinuvel fell \$3.12 or 11.0 percent to \$25.17 with 163,001 shares traded.

### [NOVA EYE MEDICAL](#)

Nova Eye says its glaucoma laser sales for the six months to December 31, 2023 rose 28 percent to \$US5.7 million (\$A8.3 million) compared to the prior corresponding period.

The company said its "strong performance during the period was driven by the commercial launch of the new Itrack Advance canaloplasty device in select markets outside of the US and China from June 2022 onwards".

Nova Eye fell half a cent or two percent to 24 cents.

### [IMEX HEALTH SERVICES](#)

Imex says receipts from customers for the year to December 31, 2022 was up 50.2 percent to \$16,304,000 compared to the previous corresponding period.

Imex said receipts for its medical software and radiology services for the three months to December 31 fell 7.5 percent to \$3,820,000 compared to the prior corresponding period.

The company said it had a \$96,000 cash burn for the three months to December 31, 2022, with cash and equivalents of \$1,912,000 at December 31, 2022, compared to \$4,186,000 at December 31, 2021.

Imex was unchanged at 44 cents.

### NEUREN PHARMACEUTICALS

Neuren says a \$US10 million (\$A15.8 million) Acadia Pharmaceuticals milestone payment has taken its customer receipts for the year to December 31, 2022 to \$15,921,000.

Last year, Neuren said the San Diego, California-based Acadia paid the milestone after the US Food and Drug Administration accepted the new drug application of trofinetide for Rett syndrome, granted priority review and assigned a Prescription Drug User Fee Act (PDUFA) action date of March 12, 2023 (BD: Oct 20, 2022).

Today, the company said that subject to approval of the NDA, it expected to receive revenue in 2023 for Rett syndrome in the US alone of \$104 million plus double-digit percentage royalties on net sales.

Neuren said the next potential milestone payment would be \$US40 million, payable following the first commercial sale of trofinetide in the US.

The company said it was \$13,433,000 cash flow positive for the three months to December 31 and \$3,599,000 cash flow positive for the 12 months to December 31, 2022, with cash and cash equivalents of \$40,180,000 compared to \$36,785,000 at December 31, 2021.

Neuren fell five cents or 0.6 percent to \$7.74 with 205,393 shares traded.

### VISIONEERING TECHNOLOGIES

Visioneering says customer receipts for the year to December 31, 2022 rose 2.1 percent to \$US7,965,000 (\$11,331,000) compared to the prior corresponding period.

Visioneering said receipts for its Naturalvue multifocal contact lenses and other myopia management products for the three months to December 31, 2022 fell 33.2 percent to \$US1,763,000 compared to the previous corresponding period.

The company said it had a \$US1,168,000 cash burn with cash and equivalents of \$US4,955,000 at December 31, 2022, compared to \$US10,985,000 at December 31, 2021.

Visioneering was up 1.5 cents or 3.75 percent to 41.5 cents.

### CRESO PHARMACEUTICALS

Creso says receipts from customers for the year to December 31, 2022 was up 29.2 percent to \$8,281,000 compared to the prior corresponding period.

Creso said receipts for its marijuana products for the three months to December 31, 2022 were up 27.4 percent to \$2,905,000 compared to the previous corresponding period.

The company said it had a \$3,430,000 cash burn for the three months to December 31, 2022, with cash and equivalents of \$1,349,000 at December 31, 2022, compared to \$7,062,000 at December 31, 2021.

Creso said that with its additional finance facilities it had 2.01 quarters of cash.

Creso was unchanged at 2.1 cents with 12.3 million shares traded.

### OVENTUS MEDICAL (IN ADMINISTRATION)

Oventus administrator Grant Thornton says the company's intellectual property has been sold for \$500,000 to Toronto's Open Airway Dental Solutions.

Last week, Grant Thornton said Oventus would enter liquidation and sell all its intellectual property to the Open Airway (BD: Jan 23, 2023).

Oventus was in a suspension and last traded at two cents.

### ONCOSIL MEDICAL

Oncosil says medical centres in Israel and Spain have treated their first commercial patients with its pancreatic cancer radiation device.

Oncosil said the first patient treated with the device in the Middle East was at Tel Aviv's Wolfson Medical Center.

The company said a patient had been treated for pancreatic cancer with the device at Clinica Universidad de Navarra in Pamplona, Spain.

Oncosil said it was "working with other institutions in Israel to treat patients with the device".

Oncosil chief executive officer and director Nigel Lange said it was "a significant achievement to treat our first patient in the Middle East and we look forward to providing hope to patients in this region with a poor prognosis from cancer of the pancreas."

"We are also pleased with the progress that we continue to make in Spain which should improve the recognition of the Oncosil device" Mr Lange said.

Oncosil was up 0.1 cents or 2.4 percent to 4.3 cents.

### PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has extended its letter of intent with Sonic Healthcare USA to licence its Promarkerd for diabetic kidney disease to February 28, 2023.

Earlier this month, the company said it had extended its letter of intent agreement with Sonic Healthcare USA until January 31, 2023 (BD: Jan 3, 2023).

Last year, Proteomics said the letter from the Texas-based Sonic Healthcare, outlined milestones, including preparing a submission to secure a proprietary laboratory analysis reimbursement code for the Promarkerd test, as well as forecasting sales targets for Promarkerd in the US (BD: Aug 9, 2022).

Proteomics fell three cents or 2.7 percent to \$1.095.

### HEXIMA

Perth's Merchant Group has failed in its bid to replace three Hexima directors with Chris Mews with more than 67.5 percent opposing the spill resolutions.

Last year, Merchant Group called for a meeting to remove Hexima directors Michael Aldridge, Jake Nunn and Scott Robertson and replace them with Merchant Group chief financial officer and company secretary Chris Mews (BD: Dec 5, 2022).

Today, Hexima said that up-to 45,639,855 votes (67.64%) opposed the four resolutions with 21,21,833,747 votes (32.36%) in favor.

Last year, Merchant Group managing-director Andrew Chapman told Biotech Daily that his company had filed the notices, and the most recent substantial shareholder notice said that Merchant held 19,686,348 Hexima shares (11.79%), sufficient to requisition extraordinary general meetings.

In June and July, Hexima fell on news that its phase II study of pezadeftide (HXP124) for onychomycosis was "inconclusive ... [and did] not support moving directly into a phase III program" and that it had begun the process of winding-up (BD: Jun 24; Jul 11, 2022).

Hexima fell 0.2 cents or 9.1 percent to two cents.

## REGENEUS

Regeneus says it has received a notice of termination from Kyocera which “purports to terminate the agreement for Kyocera’s failure to meet [a] development target”.

Regeneus said it received the notice on January 27, 2023 and Kyocera “failed to meet its development target relating to establishment of a first standard operating procedures for the manufacture of Progenza for a clinical trial to be held in Japan by the required date, being September 30, 2022”.

In 2020, Regeneus said it received a total of \$6.9 million in milestones from Tokyo’s Kyocera for its stem cell platform Progenza OA for knee osteoarthritis as part of a licence and collaboration agreement (BD: Aug 11, 28, Oct 29, 2020).

Today, the company said it was “considering its overall position in relation to the notice”.

Regeneus said Kyocera had certain rights to terminate the agreement if any target was not achieved by specified dates, subject to Kyocera “using commercially reasonable efforts to achieve the applicable development target by the date specified”.

The company said its position was that “Kyocera's lack of drug development capabilities and its allocation of insufficient resources to the development of Progenza cellular therapy for the Japanese marketplace resulted in Progenza development delays”.

Regeneus said “Kyocera did not exercise commercially reasonable efforts as defined in the agreement and Regeneus is currently considering its further legal options”.

The company said it had told Kyocera that it did not accept that Kyocera has any right to terminate the agreement; Kyocera was in material breach of its obligations under the agreement, as a result of its failure to exercise commercially reasonable efforts to achieve the applicable development target by the date specified; and considers that the failure to meet the target is due to Kyocera’s failure to fulfil its own obligations under the agreement. “It is important to note that Kyocera’s failure to meet the development target is not due to any failure by Regeneus to meet its own obligations,” Regeneus said.

The company said the parties had begun a dispute resolution process.

Regeneus chief executive officer Karolis Rosickas said the company was committed to the development and commercialization of Progenza.

“It is extremely disappointing that, after having invested so much in the relationship with Kyocera over the last two and a half years, and having fully complied with all of its own obligations under the agreement, Regeneus finds itself in a position of considering its rights and the enforcement of those rights under the agreement,” Mr Rosickas said.

Regeneus said that unless a resolution was reached, the agreement would terminate 90 days after the date of the notice.

Regeneus fell 1.9 cents or 46.3 percent to 2.2 cents with 2.75 million shares traded.

## CENTENARY INSTITUTE

The Centenary Institute says it has appointed Prof Marc Pellegrini as its executive director effective from March 1, 2023, replacing 16-year executive director Prof Mathew Vadas.

The Institute said Prof Pellegrini was a physician, immunologist and research scientist, with more than 20 years of experience working on chronic infections.

The Centenary said that Prof Pellegrini was currently the Walter and Eliza Hall Institute’s head of the Infectious Diseases and Immune Defence Division and concurrent with his appointment had been appointed as a professor at the University of Sydney.

The centenary said that Prof Pellegrini held a Bachelor of Science, and a Bachelor of Medicine and Bachelor of Surgery and a Doctor of Philosophy from the University of Melbourne.

## STARPHARMA HOLDINGS

Starpharma says it has appointed Dr Russell Basser as an independent non-executive director, effective from February 20, 2023.

Starpharma said that Dr Basser was a medical oncologist and former corporate executive with more than 30 years of medical and bio-pharmaceutical experience, including 21 years at CSL, where he was head of research and development at CSL Seqirus, CSL chief medical officer and head of clinical research and development at CSL Behring.

The company said that Dr Basser was a founding member of CSL Seqirus' executive team in 2015 as head of research and development until his retirement in April 2022.

Starpharma said that prior to joining CSL, Dr Basser was a medical oncologist at the Royal Melbourne Hospital and Western Hospital and held an appointment at the Ludwig Institute for Cancer Research.

The company said Dr Basser previously worked for AstraZeneca in the UK and was the director of the Centre for Developmental Cancer Therapeutics for seven years.

Starpharma said Dr Basser held a Bachelor of Medicine and Bachelor of Surgery and a Doctor of Medicine from the University of Melbourne, and was an author on more than 90 peer-reviewed papers, reviews and book chapters.

Starpharma fell five cents or 8.1 percent to 56.5 cents.

## RHYTHM BIOSCIENCES

Rhythm says it has appointed Sue MacLeman as an independent, non-executive director, effective immediately.

Rhythm said that Ms MacLeman had more than 30 years' experience as a pharmaceutical, biotechnology and medical technology executive and had worked for Schering Plough Corp, Amgen, Bristol-Myers Squibb and Mesoblast.

The company said that Ms MacLeman was currently the chair of MTP Connect and was currently a director of Planet Innovation.

Ms MacLeman was previously a director or chief executive officer of ASX listed companies including Anantara, Oventus, Benitec, Palla Pharma (formerly Tasmanian Poppy Industries), Novita Healthcare (formerly Avexa, now Tali Digital) and Reproductive Health Science

Rhythm said that Ms MacLeman held a Bachelor of Pharmacy from the University of Queensland, a Master of Laws from Deakin University and a Master of Marketing from Melbourne Business School.

Rhythm was up half a cent or 0.5 percent to \$1.005.