

# Biotech Daily

Tuesday October 17, 2023

# Daily news on ASX-listed biotechnology companies

- \* ASX UP, BIOTECH DOWN: VOLPARA UP 19%; PATRYS DOWN 12.5%
- \* PRIME MINISTER'S \$750k PRIZES FOR SCIENCE
- \* VOLPARA H1 RECEIPTS UP 30% TO \$21m
- \* IMEX WINS \$1.6m SAN CARLOS HOSPITAL RADIOLOGY CONTRACT
- \* ANATARA 'GARP' FOR IBS MIXED SECONDARY RESULTS
- \* RADIOPHARM: FDA OKAYS RAD301 PANCREATIC CANCER TRIAL
- \* RACE: 'INTRAVENOUS RC220 SAFE, IN RABBITS'
- \* ANTERIS ENROLS 15-PATIENT DURAVR STUDY
- \* BOTANIX: FDA 'SOFDRA' NAME CONDITIONAL OK
- \* MACH7 700k M-D 'PERFORMANCE' RIGHTS, 325k SHARES AGM
- \* ANTISENSE 'PERCHERON' NAME CHANGE, 9.7m DIRECTOR OPTIONS AGM
- \* PLATINUM REDUCES TO 12.3% OF ANTISENSE
- \* RHINOMED LOSES DIRECTOR BRENT SCRIMSHAW
- \* DR WALID AZAR REPLACES CARTHERICS CSO PROF RICHARD BOYD

#### MARKET REPORT

The Australian stock market was up 0.42 percent on Tuesday October 17, 2023, with the ASX200 up 29.6 points to 7,056.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and three were untraded. All three Big Caps fell.

Volpara was the best, up 12 cents or 18.75 percent to 76 cents, with 677,311 shares traded. Prescient climbed 12.5 percent; 4D Medical rose 7.3 percent; Alcidion was up five percent; Atomo and Cynata improved more than four percent; Micro-X was up 3.85 percent; Kazia and Nova Eye rose more than two percent; Medical Developments, Orthocell and SDI were up more than one percent; with Avita up by 0.6 percent.

Patrys led the falls, down 0.1 cents or 12.5 percent to 0.7 cents, with 4.5 million shares traded. Actinogen, Pharmaxis and Starpharma fell 10 percent or more; Resonance lost 7.25 percent; Genetic Signatures shed 6.9 percent; Emvision and Imugene fell more than four percent; Antisense, Impedimed and Proteomics were down more than three percent; Next Science and Telix shed more than two percent; Clinuvel, CSL and Pro Medicus were down more than one percent; with Cochlear, Cyclopharm, Nanosonics, Neuren, Polynovo and Resmed down by less than one percent.

#### FEDERAL GOVERNMENT

A media release from Prime Minister Anthony Albanese says the Federal Government has awarded \$750,000 in Prime Minister's Sciences Prizes.

The Prime Minister's Office said the University of New South Wales' Prof Simmons won the \$250,000 Prize for Science for her "pioneering developments in quantum computing". The Government said that University of Queensland's Prof Glenn King won the \$250,000 Prize for Innovation for research on Australian funnel web spider venom to develop drugs to treat chronic pain, epilepsy and stroke.

The Prime Minister's media release said that Monash University's Prof Chris Greening won the 2023 Frank Fenner Prize of Life Scientist of the Year for his work showing "that microbes help regulate climate change, removing harmful gases from the air".

The Government said that the \$50,000 Malcolm McIntosh Prize for Physical Scientist of the Year was won by Australian National University's Prof Yuerui (Larry) Lu, with Griffith University's Prof Lara Herrero taking the \$50,000 Prize for New Innovators.

The media release said that Judith Stutchbury won the \$50,000 Prize for Excellence in Science Teaching in Primary Schools, with Donna Buckley taking the \$50,000 Prize for Excellence in Science Teaching in Secondary Education.

Prime Minister Anthony Albanese said "the achievements of the 2023 recipients reflect the world-class quality of Australia's science and research sector and the dedication of our [science, technology, engineering and mathematics] teachers."

## **VOLPARA HEALTH TECHNOLOGIES**

Volpara said receipts for the six months to September 30, 2023 were up 29.8 percent to \$NZ22,618,000 (\$A21,024,000), compared to the prior corresponding period.

Volpara said that receipts for the three months to September 30, 2023 from its breast density and mammography monitoring software were up 31.1 percent to \$NZ11,500,000, compared to the previous corresponding quarter.

The company said the three months to September 30, 2023 was its fourth consecutive quarter of positive net operating cash flow, with about \$NZ3.4 million total operating cash flow in the 12 months to September 30, 2023.

Volpara said it had a positive cash flow for the three months of \$NZ1,231,000, with cash and cash equivalents of \$NZ13,190,000 at September 30, 2023, compared to \$NZ11,619,000 at September 30, 2022.

Volpara was up 12 cents or 18.75 percent to 76 cents.

#### IMEX HEALTH SERVICE

Imex says it has a \$1.6 million, three-year-contract with the Bogota, Colombia-based San Carlos Hospital Foundation for its Enterprise radiology imaging products.

Imex said it expected the contract to contribute \$530,000 in annual recurring revenue. Last week, the company said it had a \$2.0 million, 15-month contract with Colombia's National Police Force for its Enterprise radiology imaging at a police hospital in Bogota, Columbia (BD: Oct 11, 2023).

Today, Imex chief executive officer Dr Germán Arango said the company was "very pleased" that the San Carlos Hospital Foundation chose Imex for its radiology services. "Our capability to offer leading medical imaging technology and a team of exceptionally skilled radiology professionals played a pivotal role in our new client's decision-making process," Dr Arango said.

Imex was untraded at 60 cents.

#### ANATARA LIFE SCIENCES

Anatara says its 61-patient 'Garp' phase I/II irritable bowel syndrome trial was statistically significant for anxiety and depression but not quality of life.

Earlier this month, Anatara said stage one of the trial of gastrointestinal reprogramming, or Garp, met its primary endpoints reducing irritable bowel syndrome by 56 percent and meeting safety objectives (BD: Oct 6, 2023).

Today, the company said the trial showed a "marked improvement" for its secondary endpoints of a change from baseline in the "hospital anxiety and depression score" and a change in the quality of life of patients.

Anatara said it measured quality-of-life on three groups of 20 patients, high dose, low dose and controls, with higher values indicating a lower quality of life, and a decrease of 10 points or more a clinically meaningful improvement.

Anatara said the patients on low dose Garp went from a baseline score of 85.2 to a week 10-to-11 score of 66.5 (p = 0.29), the high dose patients went from 92.3 at baseline to 83.8 and patients receiving placebo went from a baseline of 86.8 to a score of 71.5. The company said the higher improvement in score in the placebo group, 71.5, could be "partly explained by difficulties for patients on placebo remaining in the trial" with three placebo patients dropping out from week six to week eight.

Anatara said the study used a self-test "hospital anxiety and depression score" with zero to seven meaning "normal", eight to 10 "borderline abnormal", and 11 to 21 "abnormal". The company said the low dose group baseline anxiety score fell from 9.1 at baseline to 6.3 (p < 0.001), the high dose group took a baseline score of 8.5 to 8.7 and the placebo group baseline rose from 7.9 to 9.0 at the end of the trial.

Anatara said that, for depression, the low dose group's baseline score fell from 4.2 to 2.8 (p = 0.033), the high dose patients took a baseline of 5.7 up to 6.5 and the patients receiving placebo took a baseline of 7.9 up to 9.0.

The company said it was "not surprised or concerned about the high placebo response" as irritable bowel syndrome trials typically had a high placebo response.

Anatara chair Dr David Brookes said while the company expected the quality-of-life scores to mirror the previously announced improvement in the primary endpoint of reduced irritable bowel syndrome "the highly significant improvement in anxiety and depression scores on low dose is really pleasing while noting and cautioning the small numbers".

"The p value of < 0.001 is highly promising from the overall treatment analysis of improvement in [hospital anxiety and depression scores], with the stage two design of the trial always being to confirm and or establish statistically significant p values for primary and secondary endpoints through greater numbers," Dr Brookes said.

"This analysis of these ... secondary endpoints furthers a belief that this complimentary medicine's rejuvenating gastrointestinal tract effects will provide relief for sufferers of non-specific gastrointestinal tract symptoms and be an important adjunctive therapy in mainstream medical indications, such as irritable bowel syndrome and inflammatory bowel disease." Dr Brookes said.

Dr Brookes told Biotech Daily that the trial numbers were small and not likely to provide significance values, but Garp had a method of action that had the potential for anxiety in patients with gut wall inflammation such as – irritable bowel syndrome.

Asked why the high dose was not as effective as the low dose, Dr Brookes said that "more is not always better, especially when we're delivering ingredients to specific sites".

Dr Brookes said that Garp contained pineapple stem-based bromelain, and menthol in an enteric coating which would be released in the small intestine, and butyrate, vitamin D and threonine which was released in the large intestine.

Anatara was unchanged at 2.9 cents.

#### RADIOPHARM THERANOSTICS

Radiopharm says the US Food and Drug Administration has accepted an amended investigational new drug application for an imaging trial of RAD301 for pancreatic cancer. Radiopharm said the FDA approval was in tandem with New York State Board of Pharmacy approval for distribution and allowed it to begin a nine-patient, phase I trial of RAD301, or 68Ga-Trivehexin, for detecting pancreatic ductal adenocarcinoma lesions. The company said Trivehexin was a peptide-based molecule that targeted alpha-v-beta-6-integrin, a cellular marker for tumor invasion and metastatic growth, which was found in high density in pancreatic carcinoma cells and correlated with decreased survival. Radiopharm said the study would be at New York's Montefiore Medical Center. Radiopharm chief executive officer Riccardo Canevari said the company was "very pleased that we now have the green light to start our phase I imaging trial of RAD301 in patients with pancreatic cancer, one of the highest areas of unmet medical need". Radiopharm fell one cent or 7.4 percent to 12.5 cents.

#### RACE ONCOLOGY

Race says peripheral infusion of its RC220 bisantrene formulation prevents drug precipitation and phlebitis in rabbits and in-vitro, supporting its use in clinical trials. Race said the studies of RC220, an intravenous formulation of bisantrene was performed at the San Diego, California-based Pharmaron and the University of Wollongong. The company said the current administration of bisantrene, or RC110, required a central venous catheter near or directly into the heart which had to be done in a hospital. Race said central venous catheters were common for the delivery of chemotherapy drugs to blood cancer patients but not the standard-of-practice for solid tumors like breast cancer, where peripheral intravenous infusions in an outpatient setting were preferred. The company said peripheral intravenous infusions, into the patient's arm or leg veins, could provide a better quality of life for patients with less risk and lifestyle disruption. Race said matching a drug dose for each patient was simpler using a peripheral intravenous infusion, which was important for chemotherapy where imprecise dosing could have life-threatening consequences.

The company said the data would be used in regulatory applications and patent filings and support the use of peripheral intravenous infusions of RC220 in clinical trials. Race executive director Dr Pete Smith said the study was "a key step on our path to bringing a superior version of bisantrene to the clinic for the benefit of a much larger number of patients with solid tumors and the clinicians who treat them". "With RC220 also comes additional, robust intellectual property," Dr Smith said. Race was up 6.5 cents or 8.5 percent to 83 cents.

#### **ANTERIS TECHNOLOGIES**

Anteris says it has enrolled all 15 patients in its early feasibility study of Duravr balloon-expandable, transcatheter heart valve for severe native aortic stenosis.

Anteris said the trial was "essential" for US Food and Drug Administration clearance for commercialization of its Duravr aortic heart valve product, and discharge and 30-day data would be presented on finalizing collation and analysis.

Anteris chief executive officer Wayne Paterson said "the completion of the 15-patient [study] enrolment marks another major milestone in the company's progress towards commercial approval".

Anteris fell 19 cents or 0.9 percent to \$20.30.

# **BOTANIX PHARMACEUTICALS**

Botanix says the US Food and Drug Administration has conditionally approved the name Sofdra for sofpironium bromide for excessive sweating.

Botanix said the name Sofdra was "easy to pronounce, achieved positive fit to concept, and generated strong recall scores among physicians and patients".

The company said that once the name was approved it would be used on product packaging and marketing materials, following resubmission of its new drug application to the FDA which it planned to file by April 2023.

Botanix chief executive officer Dr Howie McKibbon said "we are very pleased to receive conditional approval for Sofdra as a trade name for sofpironium bromide, as we accelerate our commercial launch preparations for the product".

Botanix was unchanged at 13.5 cents with 5.7 million shares traded.

## **MACH7 TECHNOLOGIES**

Mach7 says its annual general meeting will vote to issue managing director Michael Lampron 700,000 'performance' rights and 325,000 shares.

Mach7 said that Mr Lampron would receive 700,000 performance rights, subject to a series of milestones, additional to his \$US390,733 (\$A615,380) annual salary.

The company said shareholders would vote to issue Mr Lampron 325,000 shares "in recognition of his performance over the three-year period to June 30, 2023".

Mach7 said that shareholders would vote to issue directors Robert Bazzani and Dr Eliot Siegel 25,000 options each, exercisable at the higher of the volume 30-day weighted average market price to the date of the meeting, and the closing price on the date of issue, within five years, vesting in three equal tranches over three years.

The company said the meeting would vote to adopt its remuneration report, re-elect Dr Siegel as a director, approve the issue of securities under the long-term incentive plan, reinsert the proportional takeover provisions, approve an additional 10 percent placement facility, and approve amendments to its constitution.

The meeting will be held virtually on November 16, 2023 at 10am (AEDT). Mach7 was up half a cent or 0.8 percent to 64.5 cents.

#### ANTISENSE THERAPEUTICS

Antisense says investors will vote to change the company name to 'Percheron Therapeutics' and approve the issue of 9.7 million chair and managing-director options. Antisense said the name change positioned "it for its intended future as a leading international participant in the field of rare diseases" and that Percheron was "a breed of draft horse known for their strength, intelligence, adaptability and resolve".

The company said shareholders would vote to issue 6,690,000 options to managing-director Dr James Garner exercisable at 7.0 cents each by August 7, 2028.

Antisense said the meeting would vote to issue 3,000,000 options to chair Dr Charmaine Gittleson, exercisable at 6.1 cents each by June 30, 2028.

Antisense said the meeting would vote to re-elect Dr Gittleson, adopt its remuneration report, issue 166,990,435 shares to Platinum Asset Management, approve its employee share option plan and approve its 10 percent placement facility.

The meeting will be held online and in person at Minter Ellison, Collins Arch Level 20, 447 Collins Street, Melbourne, on November 15, 2023 at 2pm (AEDT). Antisense fell 0.2 cents or 3.2 percent to six cents.

# **ANTISENSE THERAPEUTICS**

Platinum Investment Management says it has reduced its substantial shareholding in Antisense from 11,483,140 shares (13.33%) to 11,755,158 shares (12.29%).

The Sydney-based Platinum said that on October 13 and 16, 2023 it disposed of 727,982 shares for \$47,396, or 6.5 cents a share.

#### **RHINOMED**

Rhinomed says non-executive director Brent Scrimshaw will retire effective from November 17, 2023.

The company said Mr Scrimshaw was appointed to the board on February 12, 2014 and had spent that time commercializing its technology and brands in Australia, the US and the UK.

Rhinomed chief executive officer Michael Johnson said Mr Scrimshaw had "played a vitally important role as we have built Mute into one of the leading solutions in the global sleep and snoring market".

"I would personally like to thank Brent for his support, guidance and contribution to the company and wish him the best in the future," Mr Johnson said.

Rhinomed was untraded at 2.8 cents.

#### **CARTHERICS**

Cartherics says it has appointed Dr Walid Azar as its chief scientific officer, replacing Prof Richard Boyd who will continue as chief scientific advisor, effective from today. Cartherics said Dr Azar was a molecular biologist in the research and development team at CSL, and would be responsible for its scientific activities, building its capabilities, product pipeline and platforms.

According to his Linkedin page, Dr Azar held a Bachelor of Science and a Doctor of Philosophy from the University of Melbourne.

Cartherics is a private company.