Biotech Daily

Wednesday December 18, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: CLARITY UP 12%; PERCHERON DOWN 88%**

*** PERCHERON FALLS 92% ON AVICURSEN MISSING DUCHENNE ENDPOINT**

*** CLARITY FAP RADIO-PHARMACEUTICAL FOR CANCERS**

*** CARDIEX RAISES $3.25m**

*** CARTHERICS WINS $474k G-REX GRANT FOR CTH-401**

*** AUSTCO EXPECTS H1 REVENUE UP 59% TO $37m**

*** MESOBLAST PROMOTED TO NASDAQ BIOTECH INDEX**

*** MONASH UNI: '1st COVID-19 mRNA VACCINE MAY STOP IMMUNE IMPRINTING'**

*** TRYPTAMINE: 'PSILOCYBIN LOWERS IBS STOMACH PAIN, IN 3 OF 4 PATIENTS'**

*** MEMPHASYS COMPLETES MONASH IVF FELIX RECRUITMENT**

*** NEURIZON FILES NUZ-001 FOR ALS IND TO FDA FOR HEALEY TRIAL**

*** BLINKLAB REQUESTS 'FDA OUTCOME' TRADING HALT**

*** RENERVE CHAIR STEPHEN COOPER TAKES 7.4%**

*** DR SAMUEL STRAFACE REPLACES CONTROL BIONICS CHAIR ROGER HAWKE**

*** RACE APPOINTS OPTHEA'S DR MEGAN BALDWIN DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.06 percent on Wednesday December 18, 2024, with the ASX200 down 4.6 points to 8,309.4 points. Seventeen of the Biotech Daily Top 40 companies were up, 17 fell, five traded unchanged and one was untraded.

Clarity was the best, up 56 cents or 12.15 percent to $5.17, with 3.85 million shares traded. Micro-X climbed 10 percent; Orthocell rose 9.6 percent; Nova Eye was up 6.9 percent; Atomo and Immutep improved more than five percent; Aroa, Genetic Signatures and Telix were up more than three percent; Emvision, Imugene, Mesoblast, Opthea and Pro Medicus rose more than two percent; Alcidion, CSL, Cyclopharm and Polynovo were up more than one percent; with Avita up by 0.5 percent.

Percheron led the falls (see below), down 5.2 cents or 88.1 percent to 0.7 cents, with 546.8 million shares traded. Syntara lost 10.1 percent; Actinogen was down 7.1 percent; Resonance shed 6.35 percent; Curvebeam fell four percent; Medadvisor, Proteomics and Starpharma were down three percent or more; Cynata, EBR, Neuren and Prescient shed two percent or more; Clinuvel, Cochlear, Dimerix, Impedimed and Resmed were down one percent or more; with Nanosonics and SDI down by less than one percent.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Percheron fell as much as 91.5 percent after its 48-patient, phase IIb trial of avicursen for Duchenne muscular dystrophy (DMD) did not meet its primary endpoint.

Percheron said the randomized, controlled trial did not meet its primary endpoint of an improved performance of the upper limb 2.0 score at week 25 compared to placebo.

The company said the mean change in upper limb performance score for placebo patients was down 1.4, down 1.8 in patients dosed weekly with 25mg of avicursen (p = 0.695) and down 1.6 in patients receiving 50mg of avicursen (p = 0.919) weekly.

Percheron said a p-value above 0.05 meant that any numerical difference observed was "not statistically significant".

In May, the company said that it had enrolled all 48 patients in the phase IIb study, with six-month data "expected in December 2024" (BD: May 29, 2024).

Earlier this month, Percheron said that all 48 patients completed their 25-week follow-up visits, with top-line, six-month data expected "during the week beginning December 16, 2024" and 12-month data "to be available in mid-2025 and final 16-month data [by 2026]" (BD: Dec 2, 2024).

Today, the company said there was "no statistically significant differences in efficacy on available secondary endpoints, nor was there a clear directional trend toward benefit associated with administration of avicursen".

Percheron said following the results it had determined with the investigators that it was "not in the best interests of patients or shareholders for the study to continue and has therefore resolved to terminate it as soon as practicable".

The company said it would work with the investigators and advisors to examine available data along with further data expected in January 2025 to "determine the best path forward for the avicursen program, noting in particular the drug's favorable safety profile".

Percheron said the avicursen was "safe and well-tolerated, with injection site reactions the most common treatment-emergent adverse event".

The company said "injection site reactions were more common at the 50mg dose than at the 25mg dose, but all were considered mild or moderate by investigators".

Percheron said it expected to hold a strategic review of its pipeline by July 2025 and would "share further information with investors as it becomes available".

Percheron managing-director Dr James Garner said the company was "of course disappointed by these results".

"In the more rigorous environment of a randomized, placebo-controlled, international study, avicursen has not performed in the way that we had been led to expect by earlier studies," Dr Garner said.

"The trial has not demonstrated therapeutic benefit in non-ambulant DMD," Dr Garner said. "We anticipate further data from this study in January 2025 and will be examining it closely to better understand this outcome and to assess future opportunities."

"The company is well-funded and so we can approach these discussions systematically and methodically," Dr Garner said.

"We expect to be able to share further information and plans with investors in the new year," Dr Garner said.

"In the meantime, I want to pay tribute to the investigators, healthcare professionals, and families that have placed their trust in us by participating in this study," Dr Garner said.

"Although these results may not be as we had hoped, we are proud to have played a small role in advancing understanding of the disease, and in bringing hope to those affected by it," Dr Garner said.

Percheron closed down 5.2 cents or 88.1 percent at 0.7 cents with 546.8 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has developed a fibroblast activation protein (FAP)-targeted radio-pharmaceutical for use with its copper isotopes for diagnosing and treating cancers.
Clarity said FAP was “expressed on cancer-associated fibroblasts, a particular cell type found in the tumor micro-environment”.
The company said cancer associated fibroblasts were found in a broad range of cancers including breast, colorectal, pancreatic, lung, brain and ovarian, but only minimally in normal tissue, making it “a promising pan-cancer target for both imaging and treatment”.
Clarity said it developed the copper diagnostic and therapeutic agent targeting FAP “at the benchtop of Australian science … by combining an industry leading FAP inhibitor with the proprietary Sar chelator technology”.
The company said its Sar technology allowed the use of copper-64 for imaging and copper-67 for the targeted treatment of various cancers.
Clarity said that, like its prostate specific membrane antigen-targeted prostate cancer agent dimer, Sar-bis-PSMA, which was designed to improve tumor uptake and retention, it had developed a dimer for its FAP-targeted radio-pharmaceutical, Sar-bis-FAP.
The company said mouse models had shown Sar-bis-FAP led to “increased tumor uptake and retention over 24 hours” and showed the dimer version of copper-64 Sar-bis-FAP had a higher uptake compared to the monomer version at one hour and about eight times greater retention at 24 hours.
Clarity said its dimer copper-64 Sar-bis-FAP had four times the uptake in FAP-expressing melanoma compared to the industry standard FAP-targeted monomer gallium-68 FAPI-46 and it was conducting additional investigations for a phase I trial “in late 2025”.
The company said it had begun research into the potential clinical use of its FAP agent with several pre-clinical studies in diagnostics using copper-64 Sar-bis-FAP, which would be followed by treatment opportunities of cancers using copper-67 Sar-bis-FAP.
Clarity executive chair Dr Alan Taylor said the company had created “a novel product at the benchtop to overcome the shortcomings of competing radio-pharmaceuticals by increasing the uptake and retention of the molecule over time”.
“Coupled with the use of the perfect pairing of copper isotopes, this facilitates the use of same-day and next-day imaging, addressing the issue of low sensitivity of short half-life products using gallium-68 and fluorine-18, as well as potentially enhancing the therapeutic benefit through increasing the amount and retention of the product at the site of tumors,” Dr Taylor said. “This is especially the case for FAP-targeted radio-pharmaceuticals that offer so much hope … but suffer the issue of low uptake and retention at the tumor site.”
Clarity was up 56 cents or 12.15 percent to $5.17 with 3.85 million shares traded.

CARDIEX

Cardiex says a placement has raised $3.25 million at nine cents a share, a 9.3 percent discount to the 15-day volume weighted average price.
Cardiex said investors would receive one option for each share bought exercisable at 20 cents each by November 30, 2025.
The company said the funds would be used for manufacturing, marketing and sales, expansion including scaling up supply chain operations ahead of the US launch of its Conneqt pulse device.
Cardiex said investors included directors and largest shareholder C2 Ventures Pty Ltd, which was controlled by directors Craig Cooper and Niall Cairns; with Blackpeak Capital and Stralis Capital lead managers and would receive six percent of the amount raised.
Cardiex was up 1.1 cents or 11.1 percent to 11 cents.

CARTHERICS PTY LTD

Cartherics says it has won a $US300,000 ($A474,000) G-Rex grant to support clinical manufacturing of its lead product CTH-401 for clinical trials.

Cartherics said the G-Rex grant program was a $US20 million initiative by Scaleready, Wilson Wolf Manufacturing and Cellready that was “designed to propel the advancement of cell and gene therapies”.

The company said that the grant would be used to buy equipment and reagents to support its research and manufacturing programs, specifically platform assessment, method development and up-scaling CTH-401 for clinical trials.

Cartherics chief executive officer Prof Alan Trounson said the company had “taken an ambitious step to streamline our product [research and development] and manufacturing under one roof”.

“This integrated approach positions us to seamlessly transition from pioneering pre-clinical research to clinical manufacturing, all within the same facility,” Prof Trounson said.

“The G-Rex grant will play a crucial role in advancing our research and development efforts, bringing us closer to our goal of delivering innovative treatments to patients in need, particularly in the fight against cancer and other difficult diseases,” Prof Trounson said.

Cartherics is a private company.

AUSTCO HEALTHCARE

Austco says it expects revenue for the six months to December 31, 2024 of between $35.8 million and $36.9 million, with revenue up about 59 percent.

In February, Austco said revenue for the six months to December 31, 2023 was up 11.2 percent to $22,843,000, with profit down 15.0 percent to $1,172,000 (BD: Feb 26, 2024).

Today, the company said revenue was up 19 percent from its existing operations, with the recently acquired Teknocorp and Amentco contributing between $11.8 million and $12.2 million in revenue for the six months.

Last year, Austco said it had acquired security and healthcare provider Teknocorp; and earlier this year, said it acquired certified Nurse Call reseller and healthcare solutions provider Amentco (BD: Nov 28, 2023; Feb 21, 2024).

Today, the company said it expected earnings before interest, taxation, depreciation and amortization of between $4.5 million and $5.1 million, with Ebitda up 129 percent at September 30, 2024 compared to the previous corresponding period.

Austco said its second half revenue and Ebitda were “historically higher” than the first half.

Austco chief executive officer Clayton Astles said the company’s forecast six month results show “the strength of our strategy and our ability to deliver sustained growth”.

“The integration of Teknocorp and Amentco has enhanced our capabilities, and our core business continues to perform strongly,” Mr Astles said.

Austco was up two cents or eight percent to 27 cents with 2.2 million shares traded.

MESOBLAST

Mesoblast says it has been promoted into the Nasdaq Biotechnology Index, effective from December 23, 2024.

Mesoblast said inclusion on the Index was calculated based on market capitalization.

The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

Mesoblast was up four cents or 2.1 percent to $1.98 with 8.9 million shares traded.

MONASH UNIVERSITY

Monash University says a mouse study shows Australia's first messenger RNA Covid-19 vaccine could stop 'immune imprinting', the limiting of immunity to new variants.

Monash University said 'immune imprinting' occurred when "exposure to one virus strain, acquired by way of either vaccination or viral infection, starts to limit our immunity against new variants of the virus as they arise".

The University said the Monash Institute of Pharmaceutical Sciences and Peter Doherty Institute for Infection and Immunity studied the mRNA vaccine designed to encode the proteins on the surface of the receptor-binding domain, or the tip of the virus 'spike'.

Monash University said it compared the mRNA membrane-anchored receptor-binding domain, or mRNA RBD-TM, vaccine against ancestral Covid-19 vaccines by looking at third-dose immune responses to Omicron variants.

A spokesperson for the University told Biotech Daily that the 'TM' in mRNA RBD-TM stood for 'trans-membrane'.

The University said the study showed the mRNA RBD-TM vaccine "induced a significantly stronger antibody response than ancestral vaccines".

Monash University said the ancestral vaccine comparison led to a 1.3-fold antibody increase compared with a 16.3-fold increase for the mRNA RBD-TM vaccine, despite previous exposure to Covid-19, "thus suggesting the potential to overcome the detrimental effects of 'immune imprinting'".

The University said the vaccine had already completed a phase I clinical trial with the Doherty Institute "as a fourth-dose booster against Covid-19".

Monash University said the study could help the development "a refined, homegrown vaccine to protect against Covid-19" and that next steps were testing mRNA RBD-TM in clinical trials to further validate its effectiveness against immune imprinting.

The University said the study, titled 'mRNA vaccines encoding membrane-anchored RBDs of Sars-Cov-2 mutants induce strong humoral responses and can overcome immune imprinting' was published in the journal Molecular Therapy, with the full article available at: https://bit.ly/49ZxffH.

Monash researcher and study author Prof Colin Pouton said that to protect ageing and vulnerable populations from future infections by evasive mutants, next generation Covid-19 vaccines would need to overcome the problem of immune imprinting.

"The concept of immune imprinting is not a new one - the same phenomenon occurs with influenza, and there is now mounting evidence of widespread imprinting attributed to exposure to ancestral Covid-19 strains," Prof Pouton said.

"To address this, we developed an alternative platform designed to target [severe acute respiratory syndrome coronavirus-2] Sars-Cov-2 virus mutations in the tip of the 'spike', otherwise known as the receptor binding domain," Prof Pouton said.

"We found that, when administered as a third-dose booster following two doses of ancestral vaccine, in mice, our vaccine was able to effectively induce new variant-specific antibodies, making it a promising next-generation candidate to protect against new and emerging Covid-19 strains," Prof Pouton said.

Monash Institute of Pharmaceutical Sciences researcher and study first author Dr Harry Al-Wassiti said that "another advantage to the mRNA RBD-TM vaccine is that, because it's about a quarter of the size of its whole-spike equivalents, it could be effective at lower doses, therefore making it more tolerable".

"Its smaller mRNA size also means it can be more stable at higher storage temperatures, a feature important for future mRNA vaccines," Dr Al-Wassiti said.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says three of four irritable bowel syndrome patients dosed with oral TRP-8802 psilocybin had a “clinically meaningful decrease in abdominal pain and anxiety”.
In July, Tryptamine said it had dosed the first of up-to 10 irritable bowel syndrome (IBS) patients in its phase IIa, open-label trial of oral psilocybin TRP-8802 and psychotherapy at Boston’s Massachusetts General Hospital (BD: Jul 24, 2024).
Today, the company said the preliminary results showed that three of four patients (75%) achieved a reduction in abdominal pain and gastro-intestinal associated anxiety.
Tryptamine said in “patients with pre-existing anxiety or depression there were also positive trends in improvement” and it would use the results for intra-venous psilocybin TRP-8803, including its application for patients with IBS symptoms.
Tryptamine chief executive officer Jason Carroll said the positive interim results from the first four patients in the phase IIa study provided “another strong indication of the broad potential of Tryp’s clinically-backed product suite to achieve improved patient health”.
“This interim analysis highlights that IBS is highly likely to be a viable indication for Tryptamine to pursue for commercialization with TRP-8803, I.V.-infused psilocin,” Mr Carroll said. “Tryptamine’s pipeline will be solely focused on TRP-8803, given the significant competitive advantage we see with TRP-8803 … compared to oral psilocybin.”
Tryptamine was unchanged at 3.8 cents with 1.9 million shares traded.

MEMPHASYS

Memphasys says it has completed recruitment of its 104-couple trial of its Felix sperm separation device with Monash IVF (in-vitro fertilization) Group.
In 2022, Memphasys said that with Monash IVF Group it had treated the first of up-to 104 couples in its trial to “statistically prove the Felix system is not inferior to either of the current commercial sperm separation techniques” (BD: Dec 9, 2021).
Today, the company said the results were expected to provide “validation of the Felix system's safety, efficacy and superior performance compared to traditional sperm preparation techniques, which includes density gradient centrifugation and swim-up”.
Memphasys managing-director Dr David Ali said completing the Felix registration study by the end of 2024 would be “a commercially transformative milestone”.
Memphasys was unchanged at 0.6 cents with 1.4 million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it has filed an investigational new drug application to the US Food and Drug Administration for a phase II/III trial of NUZ-001 for amyotrophic lateral sclerosis (ALS).
Earlier this year, the then Pharmaust said Massachusetts General Hospital had accepted the then monepantel, now NUZ-001, into its phase II/III Healey amyotrophic lateral sclerosis, or motor neuron disease platform trial (BD: Jul 15, 2024).
Today, the company said the milestone was “a pivotal step in enabling … a phase II/III clinical trial within the Healey ALS platform trial framework”.
Neurizon said the FDA had 30 days to review the application, and subject to approval it expected Massachusetts General Hospital to file a protocol amendment for the Healey trial to incorporate its “regimen specific appendix” by April and enrol patients by July 2025.
Neurizon managing-director Dr Michael Thurn said submitting the application was “a critical milestone in Neurizon's mission to address the devastating impacts of ALS”.
Neurizon fell half a cent or 2.9 percent to 17 cents with 1.25 million shares traded.

BLINKLAB

Blinklab has requested a trading halt pending “an announcement in relation to the [US Food and Drug Administration] pre submission outcome”.
Trading will resume on December 20, 2024, or on an earlier announcement.
Blinklab last traded down two cents or 7.55 percent at 24.5 cents.

RENERVE

Renerve director Stephen Cooper says he has increased his substantial shareholding in the company from 10,281,158 shares (7.25%) to 10,448,519 shares (7.37%).
The Melbourne-based Mr Cooper said with Zetland Road Pty Ltd he bought 167,361 shares on December 16, 2024 for $25,104, or 15.0 cents a share.
Yesterday, Mr Cooper said that with Zetland Road Pty Ltd he bought 110,370 shares on December 13, 2024 for $16,511, or 15.0 cents a share.
Renerve was up half a cent or 3.45 percent to 15 cents.

CONTROL BIONICS

Control Bionics says director Dr Samuel Straface has been appointed chair following the resignation of Roger Hawke, effective immediately.
Earlier this year, Control Bionics said it had appointed neuro-physiologist Dr Straface as a non-executive director (BD: Oct 23, 2024).
Today, the company said Mr Hawke had been director since 2018 and was chair during its initial public offering in 2020.
Control Bionics said it expressed “its gratitude for the contribution made by Mr Hawke to the growth and development of the Control Bionics business over the last six years”.
Control Bionics fell 0.1 cents or 1.6 percent to 6.2 cents.

RACE ONCOLOGY

Race says it has appointed Opthea founder and chief innovation officer Dr Megan Baldwin as a non-executive director, effective from January 1, 2025.
Last month, Opthea said executive director Dr Baldwin had stepped down from its board and would “continue to advance Opthea’s innovation agenda in her executive role as founder and chief innovation officer of the company”.
Today, Race said Dr Baldwin had more than 25 years of experience in drug development, had been a researcher at the then Genentech, now Roche, prior to founding Opthea and was currently a board member of Anaxis Pharma, Gertrude Biomedical and Ausbiotech.
The company said Dr Baldwin held a Bachelor of Science and a Doctor of Philosophy from the University of Melbourne.
Race fell 3.5 cents or 2.5 percent to $1.375.